Making Health Care Safer

A Critical Analysis of Patient Safety Practices

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Structured Abstract

Objectives: Patient safety has received increased attention in recent years, but mostly with a focus on the epidemiology of errors and adverse events, rather than on practices that reduce such events. This project aimed to collect and critically review the existing evidence on practices relevant to improving patient safety.

Search Strategy and Selection Criteria: Patient safety practices were defined as those that reduce the risk of adverse events related to exposure to medical care across a range of diagnoses or conditions. Potential patient safety practices were identified based on preliminary surveys of the literature and expert consultation. This process resulted in the identification of 79 practices for review. The practices focused primarily on hospitalized patients, but some involved nursing home or ambulatory patients. Protocols specified the inclusion criteria for studies and the structure for evaluation of the evidence regarding each practice. Pertinent studies were identified using various bibliographic databases (e.g., MEDLINE, PsycINFO, ABI/INFORM, INSPEC), targeted searches of the Internet, and communication with relevant experts.
Data Collection and Analysis: Included literature consisted of controlled observational studies, clinical trials and systematic reviews found in the peer-reviewed medical literature, relevant non-health care literature and "gray literature." For most practices, the project team required that the primary outcome consist of a clinical endpoint (i.e., some measure of morbidity or mortality) or a surrogate outcome with a clear connection to patient morbidity or mortality. This criterion was relaxed for some practices drawn from the non-health care literature. The evidence supporting each practice was summarized using a prospectively determined format. The project team then used a predefined consensus technique to rank the practices according to the strength of evidence presented in practice summaries. A separate ranking was developed for research priorities.

Main Results: Practices with the strongest supporting evidence are generally clinical interventions that decrease the risks associated with hospitalization, critical care, or surgery. Many patient safety practices drawn primarily from nonmedical fields (e.g., use of simulators, bar coding, computerized physician order entry, crew resource management) deserve additional research to elucidate their value in the health care environment. The following 11 practices were rated most highly in terms of strength of the evidence supporting more widespread implementation.

- Appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk.
- Use of perioperative beta-blockers in appropriate patients to prevent perioperative morbidity and mortality.
- Use of maximum sterile barriers while placing central intravenous catheters to prevent infections.
- Appropriate use of antibiotic prophylaxis in surgical patients to prevent postoperative infections.
- Asking that patients recall and restate what they have been told during the informed consent process.
- Continuous aspiration of subglottic secretions (CASS) to prevent ventilator-associated pneumonia.
- Use of pressure relieving bedding materials to prevent pressure ulcers.
- **Use of real-time ultrasound guidance during central line insertion to prevent complications.**
- Patient self-management for warfarin (Coumadin™) to achieve appropriate outpatient anticoagulation and prevent complications.
- Appropriate provision of nutrition, with a particular emphasis on early enteral nutrition in critically ill and surgical patients.
- Use of antibiotic-impregnated central venous catheters to prevent catheter-related infections.
Conclusions: An evidence-based approach can help identify practices that are likely to improve patient safety. Such practices target a diverse array of safety problems. Further research is needed to fill the substantial gaps in the evidentiary base, particularly with regard to the generalizability of patient safety practices heretofore tested only in limited settings and to promising practices drawn from industries outside of health care.

Chapter 21. Ultrasound Guidance of Central Vein Catheterization

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Background

The multiple indications for central venous catheters (CVCs) include parenteral nutrition, intravascular depletion, access for vasoactive medications, hemodynamic monitoring, cardiopulmonary arrest, difficult peripheral intravenous (IV) access and long-term IV access for medications, such as antibiotics. While these catheters can be life saving, they are also associated with significant risks. These risks increase in association with several characteristics, including patient anatomy (eg, morbid obesity, cachexia, or local scarring from surgery or radiation treatment), patient setting (eg, patients receiving mechanical ventilation or during emergencies such as cardiac arrest) and co-morbidities (eg, bullous emphysema or coagulopathy).

CVCs are placed by clinicians whose training and experience may vary greatly. The procedure takes place in a variety of hospital settings including intensive care units, emergency departments, operating rooms, pre- and post-anesthesia care units, hemodialysis units, cardiac catheterization units and other inpatient settings. Outpatient placement of CVCs has also become commonplace, occurring in hemodialysis centers and oncology centers providing outpatient chemotherapy.

Percutaneous insertions of CVCs are usually performed by "blind" techniques that rely on anatomic landmarks—ie, palpable or visible structures with known relationships to the desired vein. For example, the infraclavicular approach to the subclavian vein requires correct localization of the clavicle reference site, suprasternal notch and sternocleidomastoid-clavicular triangle landmarks, proper positioning of the patient and operator and correct venipuncture point depth, direction and insertion angle. Analogously, the various approaches to the internal jugular vein require thorough knowledge of this vein’s course in relation to the sternocleidomastoid muscle and carotid artery.

Newer technologies, such as portable ultrasound (US) devices, provide bedside imaging of the central veins during catheter placement. The advantages associated with US guided CVC placement include detection of anatomic variations and exact vessel location, avoidance of central veins with pre-existing thrombosis that may prevent successful CVC placement, and
guidance of both guidewire and catheter placement after initial needle insertion. This review assesses the impact of real-time ultrasound guidance on improving the safety of CVC insertions.

**Practice Description**

Real-time ultrasound guidance of CVC insertion provides the operator with visualization of the desired vein and the surrounding anatomic structures prior to and during insertion of the needle, guidewire and catheter. Previous studies of US location of vessels followed by subsequent catheter placement with landmark techniques found no advantages over standard landmark techniques. Real-time US guidance, on the other hand, appears to improve the success rate and decrease the complication rate associated with CVC placement.

Two types of real-time ultrasound guidance are described. The Doppler US guidance method include audio-guided Doppler, fingertip pulsed Doppler and probe-in-the-needle technology. The non-Doppler US guidance methods (subsequently referred to as US guidance) includes US with needle guidance or without needle guidance.

**Prevalence and Severity of the Target Safety Problem**

The annual number of all CVC insertions in the United States is not known, but is estimated at "several million" for subclavian-vein catheters. When aggregated with the various types of catheters placed into the central venous circulation and the increasing utilization of CVCs among routine surgical patients, critically ill patients (in both emergency departments and intensive care units), and for the management of many patients undergoing hemodialysis or chemotherapy, the total number of CVC placements may be many times greater than estimates for subclavian CVCs alone.

Unsuccessful insertion of CVCs may occur in up to 20% of cases. The hazards associated with attempted CVC insertion (whether successful or not) include arterial puncture, hematoma, pneumothorax, hemothorax, chylothorax, brachial plexus injury, arrhythmias, air embolus, catheter malposition and catheter knotting. Other complications associated with CVCs, such as infection, thrombosis, arterial-venous fistula and vascular or cardiac erosion, are not usually associated with needle insertion but occur after catheter placement.

The frequency of complications associated with CVC placement is quite variable, largely due to differences among selected venous insertion sites, the degree of prior operator experience and the presence of previously described risk factors. In general, the rate of major CVC complications (eg, pneumothorax or vessel laceration requiring repair) and minor complications (eg, arterial puncture without significant hemorrhage, transient catheter malposition) is between 0.5 and 10%.

In addition to complications, several quality-of-care issues are associated with problems in CVC insertion. For example, a CVC insertion that requires multiple attempts may engender considerable patient anxiety and discomfort. More importantly, a prolonged insertion process may delay the infusion of life-saving fluids or medications during an emergency.

**Opportunities for Impact**
The majority of CVC insertions are placed using the landmark method. As set forth above, the number of catheters placed annually and the proportion currently inserted without US guidance is not known. Also unknown is the proportion of catheters placed in those patients who may benefit most from the US technique—those with multiple risk factors, those in high risk settings such as the intensive care unit, or those undergoing catheter placement by inexperienced operators.

There are a variety of catheters that require access to the central veins. These include single and multi-lumen CVCs, tunneled and non-tunneled catheters, and larger, more rigid catheter introducers that permit passage of thinner, more flexible devices (eg, pulmonary artery catheters, diagnostic cardiac catheters and temporary transvenous pacemakers). All centrally-placed catheters require an initial needle insertion into the vein, followed by a guidewire to permit passage of the catheter.

Study Designs

One meta-analysis and 10 original studies were analyzed. Among the 10 original studies, 9 were randomized control studies and 1 study was a quasi-randomized control trial (see Table 21.1). The meta-analysis includes 6 references cited in this chapter. Four articles cited in this chapter were not cited in the 1996 meta-analysis, including 3 that were published after 1996 and one that included a quasi-randomized design. Two studies included in the meta-analysis were not included in this chapter because they were from non-English language journals.

All of the studies analyzed for this chapter were prospective, non-blinded and randomized, with the exception of a quasi-randomized design involving alternate week allocation of patients to receive the intervention. Randomization was at the patient (rather than physician) level in all studies.

The 10 original studies include 5 using an ultrasound guidance technique without Doppler and 5 using the Doppler US technique. Sites of catheterization included the internal jugular (IJ) veins in 6 studies, the subclavian (SC) veins in 3 studies and the femoral veins in 1 study. The study populations are diverse and include intensive care unit patients, surgical patients both preoperatively and intraoperatively, cardiac patients in both the catheterization and coronary care units, emergency department patients in cardiopulmonary arrest and oncology center outpatients.

Examples of studies excluded from analysis are studies lacking comparison control groups, studies of US use but without real-time guidance, and simulations of CVC placement rather than completed procedures.

Study Outcomes

Studies included for review reported a combination of clinical outcomes. These outcomes include Level 1 complications that resulted in increased patient morbidity (eg, pneumothorax) and Level 2 complications that represent potential adverse events (eg, unwanted arterial puncture without sequelae). Most studies also reported the number of venipuncture attempts to achieve successful CVC placement as well as the time required to complete successful CVC insertions. These are considered Level 2 outcomes because increased venipuncture attempts are associated with increased complication rates.
Evidence for Effectiveness of the Practice

The 1996 meta-analysis\textsuperscript{16} estimated that real-time US guidance for CVC insertion is associated with a significant reduction in placement failures as compared with the usual landmark techniques (relative risk 0.32, 95% CI: 0.18-0.55). In addition, this review estimated that US guidance results in decreased complications during attempted CVC placements (relative risk 0.22, 95% CI: 0.10-0.45), corresponding to a relative risk reduction of 78%.\textsuperscript{16} The mean number of attempted venipunctures till successful CVC insertion was significantly reduced with real-time US guidance (relative risk 0.60, 95% CI: 0.45-0.79), corresponding to a relative risk reduction of 40%.\textsuperscript{16}

Two of the 3 studies reviewed for this chapter and not included in the meta-analysis (because they were published subsequently) deserve mention because of contrary findings. Both 1998 studies\textsuperscript{9,17} included operators with significant prior experience placing CVCs by the usual landmark method. The overall failure rate for both landmark and US guidance techniques was very low in one study.\textsuperscript{17} The other study found statistically insignificant negative results associated with US guidance, owing to a high failure rate during the initial learning period for the newly-introduced US guidance technique, and a very low (1.3%) overall complication rate for CVC placement.\textsuperscript{9}

With the exception of femoral venous catheterization during cardiopulmonary resuscitation,\textsuperscript{15} the studies reviewed for this chapter did not find reductions in insertion time when using real-time US guidance. With 2 exceptions,\textsuperscript{9,10} the cited studies reached statistical significance for at least one of the 3 outcome measures (morbidity, potential adverse events, and number of venipuncture attempts). The most favorable outcomes associated with real-time US guidance were found in studies of inexperienced operators.\textsuperscript{6,12,13}

Potential for Harm

The additional equipment and manipulation associated with real-time US guidance for CVC insertion may increase the rate of catheter-related infections, but published studies have not included these complications. In emergency settings, the increased length of time required to place CVCs under US guidance (usually an additional 30 seconds to several minutes) may result in unacceptable delays. Potential harmful consequences resulting from real-time US guidance for CVC placement relate to changes in training and subsequent dependence on this technology. Supporters of this technology argue that increased competence and anatomic knowledge gained with US guidance will enhance performance of customary, unaided CVC placement. It is unclear if trainees who have performed CVC placement only with US assistance will have different complication rates when placing CVCs in practice settings without US equipment. Therefore, for certification of qualification, trainees may need to demonstrate competence with both US and non-US guided CVC placement.

Costs and Implementation

The major impediments to the widespread implementation of US guidance for CVC insertion are the purchase costs of the US machines. A typical machine costs $11,000-16,000 (including the probes), with a single machine able to serve most critical care units. Depending on the layout of units placing CVCs, an average 400-bed hospital would require 1-3 machines for use outside of
the operating room. (Departments of Anesthesia may require only one or two machines, as experienced anesthesiologists can continue to place most CVCs without US guidance). Hospitals in which nurses place *peripherally inserted central catheter* (PICC) lines using US guidance typically facilitate this function with a single machine, which could be dually used for CVCs depending on workflow and volume. In one study, the price of the Doppler-Smart needles (which are not required for non-Doppler US guidance) was $40-70 as compared with $3-5 for the standard needles. The cost of training new operators (including those whose only prior experience is with the landmark technique) requires further evaluation.

**Comment**

Real-time US guidance for CVC insertion, with or without Doppler assistance, improves catheter insertion success rates, reduces the number of venipuncture attempts prior to successful placement, and reduces the number of complications associated with catheter insertion. However, these benefits may not accrue until after the initial learning period for operators already experienced in the landmark techniques.

There are no studies comparing the impact of CVC insertion with US guidance on overall patient outcomes (eg, mortality, length of stay). In addition, many of the complications associated with CVC insertion are minor or easily treated. The reduction in venipuncture attempts is likely associated with reductions in the pain and discomfort associated with CVC placement, though this has not been measured.

The greatest benefit of US guidance may apply to the novice or inexperienced operator and for all operators in high-risk situations. Patients with one or more risk factors, (eg, critically ill patients on positive pressure ventilation with generalized edema and coagulopathy), may reap the greatest benefit. CVC insertion training incorporating real-time ultrasound guided techniques may provide additional valuable learning benefits for new operators. This knowledge may improve the success rate of insertion of CVCs without US guidance. Simulation training has demonstrated improved identification of the desired veins with US as compared to landmark techniques.

Finally, it should be noted that in addition to real-time US guidance, other approaches may reduce the risks associated with CVC insertion. PICC lines are gaining widespread acceptance and may be an acceptable substitute for CVCs for certain indications (eg, long-term IV access or parenteral nutrition). US guidance has also been demonstrated to improve the insertion of PICCs. Increases in the use of PICCs may help justify the purchase of ultrasound machines by individual hospitals.

For patients requiring replacement of existing CVCs, guidewire exchanges offer a way of inserting new catheters without new venipuncture attempts. A systematic review has found that guidewire exchanges are associated with fewer mechanical complications than new-site replacement, but may be associated with greater risks for catheter-related infections (Chapter 16).

Alternative methods for teaching CVC insertion skills to novices (eg, first-year resident physicians and medical students) have successfully employed multidisciplinary approaches including cadaver demonstrations. Future methods for teaching CVC insertion may employ
computerized technologies for simulations (see also Chapter 45). Haptic, or touch-related techniques use virtual reality models to create immersive simulated environments that recreate the sensation of performing a procedure.37,38 Through the use of this and other new technologies, novice operators may gain experience and confidence prior to clinical CVC insertion attempts and further improve patient safety.

### Table 21.1. Ultrasound and Doppler ultrasound guidance of central vein catheters*

<table>
<thead>
<tr>
<th>Study Setting and Population</th>
<th>Year Published</th>
<th>Intervention</th>
<th>Study Design, Outcomes</th>
<th>Relative Risk Reduction (%)†</th>
<th>Failed Catheter Insertion</th>
<th>Mean Insertion Attempts Required§</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrasound</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertiary care, teaching hospital ICU¹³</td>
<td>1990</td>
<td>US guidance for IJ CVC insertion without needle guide; concurrent feedback from an US technician</td>
<td>Level 1 Level 2</td>
<td>100 NS</td>
<td>44</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Tertiary care, teaching hospital, CT surgical patients¹⁴</td>
<td>1991</td>
<td>US guidance (7.5 and 5.0 MHz transducers) for IJ CVC insertion without needle guide</td>
<td>Level 1 Level 2</td>
<td>100</td>
<td>44</td>
<td>83 NS</td>
<td></td>
</tr>
<tr>
<td>Tertiary care, teaching hospital, cardiac patients¹¹</td>
<td>1993</td>
<td>US guidance (7.5 MHz transducer) of IJ cannulation for cardiac catheterization and CVC insertion, with needle guide</td>
<td>Level 1 Level 2</td>
<td>100</td>
<td>48</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>Urban, teaching hospital ICU¹²</td>
<td>1995</td>
<td>US guidance (7.5 MHz transducer) for SC CVC insertion with needle guide</td>
<td>Level 1 Level 2</td>
<td>86</td>
<td>48</td>
<td>90</td>
<td></td>
</tr>
<tr>
<td>Urban, teaching hospital ED, during CPR¹⁵</td>
<td>1997</td>
<td>US guidance (7.5 MHz transducer) for femoral CVC insertion without needle guide</td>
<td>Level 1 Level 2</td>
<td>71</td>
<td>54</td>
<td>100</td>
<td></td>
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<tr>
<td>Doppler Ultrasound</td>
<td></td>
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<tr>
<td>Tertiary care, teaching hospital, CT/vascular surgery patients⁸</td>
<td>1994</td>
<td>Doppler US guidance of IJ CVC insertion with probe in the needle</td>
<td>Level 1 Level 2</td>
<td>0</td>
<td>52</td>
<td>0</td>
<td></td>
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<tr>
<td>British hospital, cardiac surgery and ICU patients¹⁰</td>
<td>1994</td>
<td>Doppler US guidance of IJ CVC insertion with probe in the needle</td>
<td>Level 1 Level 2</td>
<td>-50 NS</td>
<td>17 NS</td>
<td>0</td>
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<tr>
<td>Tertiary care, teaching hospital ICU and OR; high-</td>
<td>1995</td>
<td>Audio-guided Doppler US guidance for IJ CVC insertion with probe in the needle</td>
<td>Level 1 Level 2</td>
<td>63</td>
<td>18 NS</td>
<td>88</td>
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<tr>
<td>Risk Patients</td>
<td>Year</td>
<td>Intervention</td>
<td>Success Rate</td>
<td>Level 1</td>
<td>Level 2</td>
<td>Level 3</td>
<td>Level 4</td>
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<tr>
<td>French teaching hospital ICU; low-risk patients</td>
<td>1998</td>
<td>Pulsed Doppler US guidance for SC CVC insertion without needle guide</td>
<td>Level 1</td>
<td>Level 2</td>
<td>-32(\text{§})</td>
<td>0</td>
<td>67</td>
</tr>
<tr>
<td>Tertiary care, outpatient oncology center</td>
<td>1998</td>
<td>Doppler US guidance for SC CVC insertion with probe in the needle</td>
<td>Level 1</td>
<td>Level 2</td>
<td>-46(\text{§})</td>
<td>NA</td>
<td>-53(\text{NS})</td>
</tr>
</tbody>
</table>

* CPR indicates cardiopulmonary resuscitation; CT, cardiothoracic; ED, emergency department; ICU, intensive care unit; IJ, internal jugular vein; NA, not available; NS, not statistically significant; OR, operating room; RCT, randomized controlled trial; SC, subclavian vein; and US, ultrasound guidance.

† The percentage relative risk reduction reflects the risks associated with CVC placement and the percentage change resulting from US guidance. Negative values indicate an increase in risks associated with US guidance.

§ Relative risk reduction of the insertion attempts to success reflects the relative reduction in the mean number of needle insertions attempted per patient until successful CVC placement resulting from US guidance.

References


