

Clinical Evidence and Sources

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1. United States. 2001. "Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence report/technology assessment, no. 43." Rockville, Md: Agency for Healthcare Research and Quality.
 - a. Mansfield PF, Hohn DC, Fornage BD, Gregurich MA, Ota DM. "Complications and failures of subclavian-vein catheterization." N Engl J Med 1994;331:1735-1738.
 - b. Sznajder JJ, Zveibil FR, Bitterman H, Weiner P, Bursztein S. "Central vein catheterization. Failure and complication rates by three percutaneous approaches." Arch Intern Med 1986;146:259-261.
 - c. Bernard RW, Stahl WM. "Subclavian vein catheterizations: a prospective study. I. Non-infectious complications." Ann Surg 1971;173:184-190.
2. MedPAR data from the Centers for Medicare and Medicaid Services (CMS), analyzed by KNG Consulting
 - a. Iatrogenic Pneumothorax (ICD-9 512.1) was reported in 29,691 of 12,866,082 total Medicare discharges in 2007. Infection due to central venous catheter (ICD-9 999.31) was reported in 24,420 of 11,855,943 total Medicare discharges in 2008.
3. Raptopoulos V, LM Davis, G Lee, C Umali, R Lew, and RS Irwin. 1991. "Factors affecting the development of pneumothorax associated with thoracentesis". AJR. American Journal of Roentgenology. 156 (5): 917-20.
4. Zhan C, M Smith, and D Stryer. "Incidence, Outcomes and Factors Associated with Iatrogenic Pneumothorax in Hospitalized Patients" [abstract]. In: AcademyHealth Annual Research Meeting.; 2004; San Diego, Calif. AcademyHealth. 2004; 21: abstract no. 1862.
 - a. "Depending on age and comorbidities, iatrogenic pneumothorax was associated with 4 to 7 excess days in length of stay, between \$17,000 and \$45,000 in excess charges, and 1% to 14% in excess mortality."
5. For information on CMS' quality reporting/value based purchasing program, please see: <http://www.sonosite.com/improvecare/evidence> to view a complete list of sources and related links.
6. "Injuries and Liability Related to Central Vascular Catheters—A Closed Claims Analysis", Domino et al. Anesthesiology 2004; 100:1411-8.
7. United States. 2001. "Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence report/technology assessment, no. 43." Rockville, Md: Agency for Healthcare Research and Quality.
 - a. Randolph AG, DJ Cook, CA Gonzales, and CG Pribble. 1996. "Ultrasound guidance for placement of central venous catheters: a meta-analysis of the literature". Critical Care Medicine. 24 (12): 2053-8.
8. Karakitsos D, N Labropoulos, De Groot E, AP Patrianakos, G Kouraklis, J Poularas, G Samonis, DA Tsoutsos, MM Konstadoulakis, and A Karabinis. 2006. "Real-time ultrasound-guided catheterisation of the internal jugular vein: a prospective comparison with the landmark technique in critical care patients". Critical Care (London, England). 10 (6): R162.
9. Feldman JP, Gould, MK. "Crossing the Line." Medicine, March 2004.
10. Stone MB, Nagdev A, Murphy MC, Sisson CA. "Ultrasound detection of guidewire position during central venous catheterization." Am J Emerg Med. 2010 Jan;28:82-84.
11. American Board of Internal Medicine. 2009. "Internal Medicine & Subspecialty Policies | Become Certified by ABIM | American Board of Internal Medicine." (accessed January 15, 2010).
12. Feller-Kopman D. "Ultrasound-Guided Thoracentesis." Chest 2006;129:1709-1714.
13. Feldman JP, Gould, MK. "Crossing the Line." Medicine, March 2004.

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How Often do Complications Occur?

Central Venous Catheter Complications

- Unsuccessful insertion. The Agency for Healthcare Research & Quality (AHRQ) reports that unsuccessful insertion of central venous catheters (CVCs) occur in up to 20% of all cases.¹
- Total complications. The rate of major and minor CVC complications is up to 10%. These complications are: ¹
 - Arterial puncture
 - Hematoma
 - Pneumothorax
 - Hemothorax
 - Chylothorax
 - Brachial plexus injury
 - Arrhythmias
 - Air embolus, catheter malposition
 - Catheter knotting

Iatrogenic Pneumothorax (IP)

- MedPAR data from the Centers for Medicare and Medicaid Services (CMS) indicates that IP was reported in 2.31 per 1,000 discharges in 2007.²
- As many as 18% of thoracentesis are complicated by pneumothorax.³

What is the Cost of Complications?

Iatrogenic Pneumothorax

- AHRQ reports iatrogenic pneumothorax is associated with an increased length of stay of 4-7 days.⁴
 - The attributable cost per incident is \$17,000 – \$45,000.
- Under Medicare’s Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program, facilities must report rates of iatrogenic pneumothorax to receive the full market basket update; these data will be public beginning in 2010.⁵

What is the Cost of Medical Malpractice Associated with Complications?

An analysis of claims related to injury resulting from central venous catheter placement (part of the American Society of Anesthesiology Closed Claims Project) reveals that “claims related to central catheters had a high severity of patient injury” and resulted in the following payments:⁶

| Type of Complication | Median Payment | Range of Payment |
|-------------------------------------|----------------|------------------------|
| Wire/Catheter embolus | \$39,725 | \$654 – \$132,500 |
| Cardiac tamponade | \$160,245 | \$34,499 – \$6,912,000 |
| Carotid artery puncture/cannulation | \$40,870 | \$12,975 – \$527,000 |
| Hemothorax | \$297,000 | \$17,850 – \$1,435,293 |
| Pneumothorax | \$143,250 | \$1,280 – \$208,750 |
| Miscellaneous vessel injury | \$184,625 | \$1,000 – \$1,717,775 |
| All central catheter claims | \$105,500 | \$654 – \$6,912,000 |

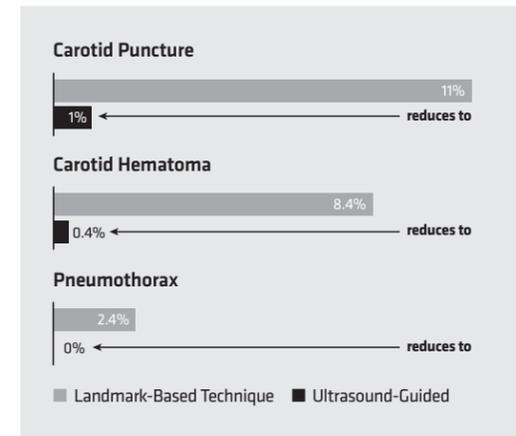
Data in 1999 dollars; claims against anesthesiologists since 1970.

Ultrasound Guidance Reduces These Risks and Improves the Quality of Care

Central Venous Catheters

The AHRQ recommends ultrasound guidance for all central venous cannulation.

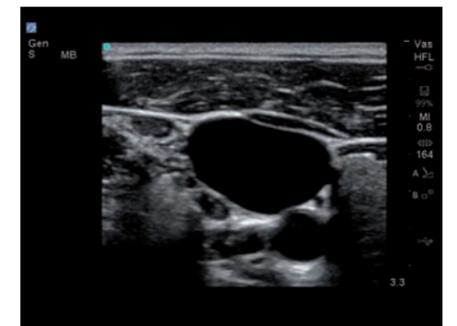
- Reduces placement failures and complications during attempted placements with a relative risk reduction of 78%.⁷
- In 900 critical care patients, ultrasound guidance of internal jugular vein catheterization reduced complications dramatically as seen to the right.⁸
- Carotid puncture was reduced from 8.3% to 1.7%.⁹
- Reduces the number of venipuncture attempts prior to successful placement.⁷
 - Avoids patient anxiety and discomfort from multiple attempts.
 - Speeds the care process during an emergency.
- Reliable detection of the guidewire with ultrasound guidance during CVC placement provides an additional measure of safety.¹⁰



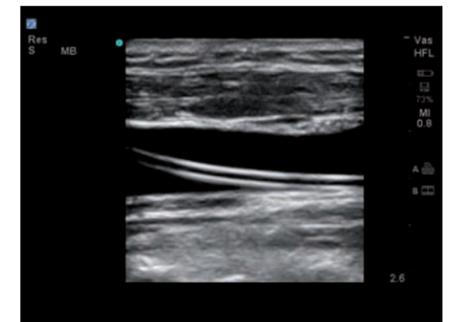
Thoracentesis & Paracentesis

The American Board of Internal Medicine strongly recommends proficiency in use of ultrasound to guide thoracentesis for certification in the subspecialty of critical care medicine.¹¹

- Reduces the rate of pneumothorax resulting from thoracentesis to 3% or lower (vs. 18% without ultrasound).³
- Ultrasonography is advantageous over standard chest radiography and CT because of the absence of radiation.¹²
- 95% of patients with ascites were successfully aspirated using emergency center ultrasound technique versus 61% using the traditional technique.¹³



Transverse View Internal Jugular Vein



Sagittal View Internal Jugular Vein with Catheter in Lumen

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