

Reporting Standards for Central Venous Access

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Abbreviation: CVAD = central venous access device

CENTRAL venous access has become an integral component of modern medical care. Central venous access is defined as catheter placement with the tip positioned at the caval atrial region (1). The purpose of this document is to provide guidelines for reporting the methods and results of central venous access device (CVAD) studies (Table 1). Standardized reporting allows for comparison of the strengths and limitations of different devices, device insertion techniques, postprocedure care routines, and procedures to salvage device failure (2). The following CVAD reporting guidelines present the elements that should be documented in a study.

PATIENT SELECTION AND INDICATIONS

Discussion.—Documentation of demographic information allows for comparison of study populations from different reports. Basic demographic information includes age, sex, and underlying disease. Additional information that characterizes the study population includes history of previous CVAD insertion, presence of coagulopathy, potential risk factors for CVAD infection (eg, fever, sepsis, known infection, or immunodeficiency), mental competence, nu-

tritional status/weight, hospitalization at the time of the procedure, and patient preference for a particular type of CVAD (3-7).

CVAD historical information includes indication for use, device type, access site, duration of use, and reason for device removal. A history of a previous indwelling central venous catheter may potentially affect the selection of a particular device or may limit available sites for access. For example, dialysis catheters inserted by the subclavian vein approach have been shown to result in an increased incidence of central venous thrombosis and/or stenosis (8-10). A history of previous arm, neck, or chest surgery/trauma or presence of a cardiac pacemaker may limit viable venous access sites.

Patients with a history of previous CVAD complications such as inadvertent catheter removal, catheter occlusion, central venous thrombosis or stenosis, fibrin sheath formation, or catheter-related infection may be at increased risk for future CVAD complications. However, no system currently exists to accurately define patient populations at increased risk for central venous access procedure complications.

Indications for insertion of a CVAD include long-term administration of intravenous medications, hemodialysis, plasmapheresis, administration of intravenous medications that may be harmful to peripheral venous endothelium, simultaneous administration of medications that cannot be mixed, and frequent blood sampling (1).

Recommendations for Reporting Standards.—State the selection and exclusion criteria for study subjects and controls. Provide relevant demographic and historical information for study subjects. Patient informed consent and institutional review board approval, where appropriate, should be documented. Report the indications for CVAD insertion.

DEVICE DESCRIPTION

Discussion.—A **tunneled catheter** is defined as a central venous catheter that travels through a subcutaneous tract before entering the access vein. A subcutaneous infusion **port** consists of a tunneled central venous catheter that terminates in a subcutaneous pocket where a self-sealing reservoir is implanted (1). The tunneled catheter exit site or implanted port pocket is usually placed over the upper chest or the upper extremity near the antecubital fossa (11-16). Reports have described alternate access routes for tunneled central venous catheters including transfemoral, translumbar, and transhepatic (17-21).

Recommendations for Reporting Standards.—A device description should include device category (tunneled or untunneled) and device specifications (Table 1).

PROCEDURE DESCRIPTION

Recommendations for Reporting Standards.—The CVAD insertion technique description should be sufficiently detailed to allow the proce-

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ture to be consistently reproduced by others. The description of a novel technique should specify the differences from standard techniques.

ASEPTIC PRECAUTIONS

Discussion.—Studies comparing the outcomes of CVADs placed in surgical operating rooms and interventional radiology suites have shown comparable results (22–24).

Patient skin preparation routines vary. Some routines involve the use of iodophor scrub, iodophor paint, isopropyl alcohol, chlorhexidine, or a combination of agents (25). There is currently no consensus as to the routine use of prophylactic antibiotics (26–28).

Recommendations for Reporting Standards.—Indicate the type of procedure room used, such as interventional radiology suite, surgical operating room, or general radiology/fluoroscopy room. Describe relevant procedure room protocols such as use of hats, masks, gowns, operator scrub routine, instrument tray preparation, and patient skin preparation.

Specifically state whether prophylactic antibiotics are routinely administered. State the name, dose, time of administration relative to the procedure, frequency, duration, and route of administration of prophylactic antibiotics. Indicate whether the patient is febrile or is receiving antibiotics for treatment of an existing infection, presumed infection, or continuous prophylactic antibiotics.

OPERATOR/INSTITUTIONAL EXPERIENCE

Discussion.—Studies have been performed comparing outcomes of CVAD placement, using operators with variable experience. Some series have encountered lower complication rates for procedures performed by experienced operators (29,30).

Recommendations for Reporting Standards.—Indicate operator and institutional experience with the device used in the study.

ANESTHESIA

Recommendations for Reporting Standards.—Report the types and routes of administration of anesthetic or

Table 1
CVAD Reporting Guidelines

	R	hr	r
MATERIALS AND METHODS			
Patient Data			
Patient selection/exclusion criteria	X		
Patient demographic information			
Age	X		
Sex	X		
Underlying disease		X	
Comorbid illness			X
History of previous CVAD			
Indication			X
Device type			X
Access site			X
Duration of use			X
Complications			X
Reason for device removal			X
Presence of coagulopathy			X
Potential risk factors for CVAD infection			X
Mental competence			X
Nutritional status/weight			X
Inpatient/outpatient			X
Indication for central venous access	X		
CVAD Description (Due to the variability of the goals of CVAD studies, all of the descriptive elements are not listed as requirements. The elements in the text of a report should be tailored to the goals of the study.)			
Category			
Tunneled			
Untunneled			
Specifications			
Brand name/manufacturer			
Composition			
Coating			
Number of lumens			
Number of catheters			
External catheter diameter			
External catheter shape			
Internal luminal diameter(s)			
Internal luminal shape(s)			
Number/size of side holes			
Configuration of catheter tip			
Subcutaneous cuff			
Method of device fixation to skin/subcutaneous tissues			
External interface			
Flow characteristics			
Procedure Description			
Aseptic precautions			
Procedure room	X		
Antibiotics	X		
Mask, cap, gown, etc.	X		
Operator/institutional experience			X
Anesthesia			X
Device insertion			
Initial venous access			
Selection of venous puncture site			X
Patient positioning			X
Vein localization			
Imaging guidance	X		
Access needle	X		
Coaxial access system			X
Catheterization attempts			X
CVAD insertion	X		

Table 1 continues

Table 1
Continued

	R	hr	r
Wound closure and dressing	X		
Post-procedure imaging	X		
CVAD Maintenance			
Maintenance provider		X	
Dressing routine		X	
Catheter flush routine		X	
OUTCOME EVALUATION			
Follow-up			
Method			
Prospective or retrospective	X		
Interval		X	
Duration	X		
Imaging studies			X
CVAD survival			
Technical success/failure	X		
Initial device service interval	X		
Revised device service interval(s)	X		
Revisions per 100 catheter days	X		
Revisions per access site	X		
Total access site service interval	X		
Complications			
Diagnosis/management		X	
Early	X		
Late	X		
Infections per 100 catheter days	X		
Malfunctions per 100 catheter days	X		
Cost			X

Note.—R = required, hr = highly recommended, r = recommended.

sedative agents. Report the number of procedures performed with the assistance of an anesthesiologist.

DEVICE INSERTION

The device insertion procedure is divided into initial venous access, device insertion and positioning, wound closure and wound dressing, and postprocedure imaging.

Initial Venous Access

Discussion.—Patient position may potentially affect the likelihood of a successful central venous access procedure (31,32). External or fluoroscopic landmarks, venography, and sonography are used for localization of the internal jugular, subclavian, axillary, and upper extremity veins (31–46). The sonographically guided internal jugular vein approach has been shown to have a lower complication rate compared to external landmark-guided puncture (42–46). Venous recanalization and/or angio-

plasty are sometimes required to achieve adequate catheter position during the central venous access procedure (47).

Recommendations for Reporting Standards.—State the method and route of venous access. Include patient positioning, technique for vein localization, and venous puncture site selection. For sonographically guided access, indicate the type/frequency of sonographic transducer and whether a needle guide is used. Include the diameter of the access needle for percutaneous venous access and whether a coaxial access system is used.

Indicate the number of catheterization attempts. The number of vein catheterization attempts is defined as the number of access needle passes made through the skin to obtain venous access. Record any inadvertent arterial punctures.

Report any venous abnormalities such as stenosis and occlusion, and any interventions such as recanalization, angioplasty, and stent insertion

required to achieve access. Report any relevant variant anatomy such as the presence of a left superior vena cava. Record any failures to obtain venous access at a particular site.

CVAD Insertion

Discussion.—The ideal tip location for central venous access catheters has yet to be determined. One study has shown that positioning the catheter tip in the high superior vena cava is associated with an increased complication rate (48). Alternatively, case reports have indicated that a central venous catheter positioned deep within the right atrium or right ventricle can potentially result in cardiac perforation (49–52). Studies have indicated that the catheter tip may migrate when the patient position is changed from supine to upright (53,54).

During the CVAD insertion procedure, the catheter tip is usually positioned with the aid of fluoroscopy. Some studies have used electrocardiographic monitoring of the catheter tip (55,56) and a catheter tracking device (12,13) to position the catheter tip.

Recommendations for Reporting Standards.—Report relevant technical information such as use of a peel-away sheath (diameter, length, and shape), guide wire (type and diameter), and subcutaneous tunneling device (sharp or blunt tip). Describe the techniques used to determine catheter length, position the catheter tip, and to construct the subcutaneous pocket/tunnel. Describe any unsuccessful device insertion attempts or changes from the initially planned device. Report the technique for securing the device to the subcutaneous tissues or to the skin.

Wound Closure and Dressing

Discussion.—Variables such as wound irrigation, materials and technique for wound closure, use of topical antibiotics, and wound dressing may affect CVAD outcome (57–59).

Recommendations for Reporting Standards.—Describe the techniques and materials used for wound irrigation, wound closure, and wound dressing.

Table 2a
Early Complications (Usually <24 Hours)

Persistent bleeding at venous puncture site
 Persistent bleeding at catheter exit site
 Soft tissue swelling
 Hematoma
 Cardiac arrhythmia
 Arterial injury
 Venous injury
 Cardiac perforation
 Arteriovenous fistula
 Intimal injury
 Venous thrombosis
 Vasovagal reaction
 Pneumothorax
 Hemothorax
 Air embolism
 Allergic reaction
 Contrast reaction
 Persistent pain at catheter site
 Anesthetic-related complications
 Inability to access device
 Catheter kinking
 Suture occlusion of catheter

Table 2b
Early Complications (<30 Days)

Catheter tip migration
 Catheter occlusion
 Catheter fragmentation
 Inadvertent catheter removal
 Catheter-port/hub connection failure
 Wound dehiscence
 Venous thrombosis
 Extremity swelling
 Infusate infiltration around access device
 Inability to access the device
 Catheter-related infection

Table 3
Late Complications (>30 Days)

Catheter-related infection
 Venous thrombosis
 Extremity swelling
 Catheter tip migration
 Venous perforation
 Cardiac perforation
 Cardiac arrhythmia
 Inadvertent device removal
 Catheter-port/hub connection failure
 Catheter fracture
 Catheter occlusion/fibrin sheath formation
 Catheter erosion through vessel wall
 Erosion of port/catheter through the skin
 Infusate infiltration around access device
 Inability to access the device

Recommendations for Reporting Standards.—Document the postprocedure catheter maintenance protocol. Describe the catheter flush and dressing routine. Report the timing of initial device access and/or use after the insertion procedure. Indicate the catheter maintenance provider such as the patient or personnel specialized in dressing changes. State the protocol for catheter exchange over a guide wire if it is part of routine access maintenance. Routine use of systemic anticoagulants to maintain catheter patency should be noted.

FOLLOW-UP

Discussion.—**Technical success** is defined as catheter introduction into the venous system with the tip positioned in the desired location, and with adequate catheter function (1). Withdrawal of blood for sampling and infusion of saline into the device without significant resistance are indicators of successful catheter function. For tunneled hemodialysis catheters in adult patients, 300 mL/min is considered an adequate rate of blood flow (67).

Device failure is defined as any limitation in catheter function despite technically successful catheter placement. Examples of device failure include inadequate rate of blood flow through a hemodialysis catheter and failure of one lumen in a multiple lumen device. CVAD exchange over a guide wire as part of routine access maintenance is not considered a device failure. The cause of device failure is usually a result of a device-related complication. This differs from

disease-related reporting standards in which a procedure failure may be due to progression of the disease, such as recurrent vessel stenosis.

Initial (primary) device service interval is defined as the number of catheter days from CVAD insertion until removal at the completion of therapy, patient death, conclusion of the study with the catheter still functioning, or device failure.

Revised (secondary) device service interval is defined as the service interval that begins after device replacement or salvage without abandonment of the access site. Examples of interventions include device exchange over a guide wire, fibrin sheath stripping, thrombolytic infusion directly into a catheter, catheter tip repositioning, kinked catheter repositioning, and replacement/repair of a CVAD component (68–72). Each device revision results in the start of a new revised (secondary) device service interval.

Total access site service interval is defined as the sum of all device service intervals at a single access site. This accounts for devices replaced or manipulated due to device failure, but maintaining the original venous access site. Replacement of an inadvertently removed catheter through the existing subcutaneous tunnel results in a new device service interval, but does not end the access site service interval (73,74).

Postprocedure Imaging

Discussion.—Imaging may include fluoroscopy, a supine or upright chest radiograph, and contrast injection through the catheter (60–63). Postprocedure radiographs are routinely used to exclude pneumothorax. One study has suggested that a postprocedure chest radiograph may not be routinely needed after image-guided insertion of internal jugular central venous catheters (64).

Recommendations for Reporting Standards.—Describe the imaging method used at the completion of the procedure to evaluate for pneumothorax, catheter kinking, and catheter tip position.

MAINTENANCE

Discussion.—Several centers have established an expert infusion-therapy team for the insertion and maintenance of catheters. One study has shown that such a team can decrease the infection rate (65).

In a prospective randomized study, low-dose oral anticoagulation significantly decreased the incidence of thrombotic complications of CVADs (66).

Table 4
Definitions of Catheter-Related Infection (24, 79, 80)

<p>Phlebitis: Mechanical or chemical inflammation of a vein as evidenced by pain, erythema, swelling, or a palpable venous cord. Septic phlebitis is the development of phlebitis associated with bacteremia and fever.</p> <p>Catheter-related sepsis: Growth of organisms on the catheter tip and in the blood, with no other source of infection, and clinical signs and symptoms of sepsis.</p> <p>Exit site infection: Erythema, tenderness, induration, and/or purulence within 2 cm of the catheter exit site in the absence of bacteremia.</p> <p>Tunnel infection: Erythema, tenderness and/or induration along the subcutaneous tract of a catheter at more than 2 cm from the skin exit site. A rare variation of tunnel infection is clavicular osteomyelitis.</p> <p>Pocket infection: Erythema, tenderness, induration, and/or purulence within/overlying the subcutaneous port pocket.</p> <p>Wound infection: Erythema, tenderness, induration, and/or purulence at a skin incision site.</p> <p>Sepsis of unknown origin, probably not catheter-related: Sepsis in a patient with an asymptomatic catheter without a known focus of infection in whom fever and bacteremia do not resolve within 48 hours of catheter removal and negative catheter tip culture.</p> <p>Sepsis of unknown origin, probably catheter-related: Sepsis in a patient with an asymptomatic catheter with no known focus of infection, which resolves within 48 hours of catheter removal. Catheter-related bacteremia is defined on the basis of positive blood cultures, regardless of the results of the catheter tip culture.</p> <p>Sepsis: One positive blood culture result with symptoms and signs of infection.</p> <p>Bacteremia: One positive blood culture result. An asymptomatic catheter removed for fever without bacteremia, with a negative catheter-tip culture, is not considered a catheter-related infection.</p> <p>Catheter colonization: Growth of >15 colony-forming units from the catheter tip without other evidence of infection.</p>
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Recommendations for Reporting Standards.—Report the technical success rate for CVAD insertion. Indicate the reasons for technical failures. Report the follow-up method, interval, and duration. State whether follow-up analysis is prospective or retrospective. CVAD survival data should be analyzed with the use of the Kaplan-Meier or life-table method (75–77). Initial device service interval, revised device service intervals, and total access site service interval should be reported as a total, mean, median, and range of catheter days. When reporting revised device service intervals, the service interval after each revision (first, second, third, etc) should be reported separately. State the reason for device removal. Report the number and type of CVAD revisions per 100 catheter days and mean number of catheter revisions per access site.

Report any significant limitations in device function. Report procedures required to restore device function. Data regarding the use of intracatheter thrombolytic agents to treat catheter occlusion may be difficult to obtain. Reporting the use of intracatheter thrombolytic agents is not required. However, the report should specifically indicate that the use of intracatheter thrombolytic agents is not included in the calculation of the device revision rate.

Results of catheter tip cultures, if performed, should be noted. Follow-up imaging studies, such as sonography or venography, specifically performed to evaluate possible catheter malfunction or complication should be documented.

For deceased patients, the last entry in the hospital or office chart is considered the last date of follow-up if the family and/or the patient's physician cannot be interviewed. Patients are considered lost to follow-up if either the investigator or the patient's physician could not contact the patient or the patient's family.

COMPLICATIONS

Discussion.—Grading of complications quantifies the morbidity caused by a procedure (2). **Early complications (Tables 2a, 2b)** occur within 30 days of the procedure and **late complications (Table 3)** occur after 30 days of the procedure. Most of the early complications are related to the technique of placing the CVAD and are more likely to be encountered within 24 hours of the procedure. However, some procedure-related complications may not be recognized until days or weeks after the procedure. For example, a catheter tip malposition at the time of the procedure

may only become apparent weeks after the procedure when an occlusive fibrin sheath forms, or when the patient becomes symptomatic from cardiac arrhythmia. A delayed pneumothorax may not be detected for hours to days following the procedure (78,79).

Infectious complications may occur early or late. Definitions of catheter-related infection are listed in **Table 4**. Often catheters are removed in the setting of a fever without sepsis for presumed catheter-related infection. If a catheter was removed for fever only, but the catheter-tip culture was negative, this should not be considered a catheter-related infection.

Early infectious complications are usually related to a breach in sterile technique at the time of device insertion and become clinically apparent in the early post-procedural period. There are several methods for documenting catheter-related infection including peripheral blood culture, blood culture drawn from the CVAD, quantitative blood culture, catheter culture, and the Maki method (24,80–84).

Recommendations for Reporting Standards.—List (Appendix 2) and grade (Appendix 1) complications according to the definitions of the SIR. Report complications as early or late. Indicate the absence of complications

encountered at the time of the procedure.

Report the criteria used for catheter removal or abandonment of an access site. Describe the diagnostic evaluation and management of specific complications. Report the number of complications as a function of the device/access site service interval as the number of complications per 100 catheter days. Infection-free catheter survival data should be analyzed with the use of the Kaplan-Meier or life-table method (75–77).

Describe the method and criteria used to determine catheter-related infection. Discuss the protocol for diagnosis and management of suspected catheter-related infection or catheter-related sepsis. Report catheter change and catheter removal criteria when catheter-related infection is suspected.

COST

Discussion.—Cost analysis provides an evaluation of resource utilization (85). Factors that contribute to the total cost for CVAD insertion include direct material costs such as the venous access device, catheters, guide wires, needles, syringes, drapes, surgical instruments, dressings, contrast material, anesthetic agents, and antibiotics. After the CVAD insertion procedure, follow-up costs include catheter maintenance, reinterventions, and episodes

of infection that require antibiotics or hospitalization, and device removal. Cost may be affected by inpatient or outpatient procedure, location of the procedure such as an interventional radiology suite or a surgical operating room, participation of an anesthesiologist, use of a postprocedure recovery area, and the use of imaging studies such as venography or sonography.

Image-guided percutaneous placement of venous catheters and ports has become the method of choice in many institutions because it has reduced morbidity and mortality and has helped reduce costs and hospital length of stay (1). There is decreased cost of CVAD placement by radiologists, because of the money saved by not using an operating room, recovery room, or the anesthesia service (86,87).

Recommendation for Reporting Standards.—No standard has been established for the reporting of procedure and CVAD maintenance costs. However, a study that includes cost analysis must define how the costs are calculated. List the resources consumed by the procedure separate from the calculated costs. Distinction should be made between cost and patient charge.

CONCLUSION

CVAD insertion has become a common procedure performed by inter-

ventional radiologists (86,88–92). Many variables are involved in CVAD selection, insertion, management, and follow-up. The purpose of this document is to provide standardized definitions and uniform reporting requirements to assist in study design and outcomes reporting. This document attempts to guide future studies toward a consistency of reporting that will allow comparisons among studies from different institutions.

APPENDIX 1

SIR CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

- A. No therapy, no consequence
- B. Required nominal therapy, no consequence; included overnight admission for observation

Major Complications

- C. Required therapy, minor hospitalization (<48 hours)
- D. Required major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours)
- E. Permanent adverse sequelae
- F. Death

APPENDIX 2

SIR COMPLICATIONS MASTER LIST

Complication	Complication class
Abscess	Infectious/inflammatory
Angina/coronary ischemia	Cardiac
Idiosyncratic reaction	Medication related
Allergic/anaphylactoid reaction	Contrast related
Arrhythmia	Cardiac
Arterial occlusion/thrombosis, puncture site	Vascular
Arterial occlusion/thrombosis, remote from puncture site	Vascular
Arteriovenous fistula	Vascular
Congestive heart failure	Cardiac
Contamination of pleural cavity (urine, bile, malignancy, empyema, other)	Respiratory/pulmonary
Device malfunction with adverse effect	Device related
Death related to the procedure	Death
Death unrelated to procedure (30-day mortality)	Death
Embolization, arterial	Vascular
Fluid/electrolyte imbalance	General nonvascular
Hematoma bleed, remote site	Vascular
Hematoma bleed at needle, device path: nonvascular procedure	Vascular
Hematoma bleed, puncture site: vascular procedure	Vascular
Incorrect drug	Medication related
Incorrect dosage	Medication related
Intimal injury/dissection	Vascular
Ischemia/infarction of tissue/organ	Vascular
Incorrect site of administration	Medication related
Local infection	General nonvascular
Liver failure	General nonvascular
Migration	Device related
Myocardial infarction	Cardiac
Malposition	Device related
Nausea/vomiting	General nonvascular
Other (cardiac)	Cardiac
Other (contrast related)	Contrast related
Other (CNS complication)	Neurologic
Other dose-dependent complication	Contrast related
Other (device related)	Device related
Other (gastrointestinal)	General nonvascular
Other (hematologic)	General nonvascular
Other (infectious/inflammatory)	General nonvascular
Other (medication related)	Medication related
Other (neurologic)	Neurologic
Other pleural complication	Respiratory/pulmonary
Other (vascular)	Vascular
Pancreatitis	Infectious/inflammatory
Pulmonary embolism	Respiratory/pulmonary
Pulmonary embolism	Vascular
Peritonitis	Infectious/inflammatory
Hypotension	Cardiac
Hypoxia	Respiratory/pulmonary
Pulmonary edema	Respiratory/pulmonary
Peripheral nervous system complication	Neurologic
Pneumothorax	Respiratory/pulmonary
Pseudoaneurysm	Vascular
Respiratory arrest	Respiratory/pulmonary
Renal failure	Contrast related
Septicemia/bacteremia	Infectious/inflammatory
Seizure	Neurologic
Septic shock	Infectious/inflammatory
Stroke	Neurologic
Tissue extravasation	Contrast related
Transient ischemic attack	Neurologic
Unintended perforation of a hollow viscus	General nonvascular
Vascular perforation or rupture	Vascular
Vagal reaction	Cardiac
Vasospasm	Vascular
Venous occlusion/thrombosis, puncture site	Vascular
Venous occlusion/thrombosis, remote from puncture site	Vascular

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