



CAR Standards for the Performance of Percutaneous IVC Filter Placement

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The standards of the Canadian Association of Radiologists (CAR) are not rules, but are guidelines that attempt to define principles of practice that should generally produce radiological care. The physician and medical high-quality physicist may modify an existing standard as determined by the individual patient and available resources. Adherence to CAR standards will not assure a successful outcome in every situation. The standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The standards are not intended to establish a legal standard of care or conduct, and deviation from a standard does not, in and of itself, indicate or imply that such medical practice is below an acceptable level of care. The ultimate judgment regarding the propriety of any specific procedure or course of conduct must be made by the physician and medical physicist in light of all circumstances presented by the individual situation.

Pulmonary embolism (PE) continues to be a major cause of morbidity and mortality in the United States. Estimates of the incidence of nonfatal PE range from 400,000 to 630,000 cases per year, and 50,000-200,000 fatalities per year are directly attributable to PE (1-4). The current preferred treatment for deep venous thrombosis (DVT) and PE is anticoagulation. However, up to 20% of these patients will have recurrent PE (1, 5, 6).

Interruption of the inferior vena cava (IVC) for the prevention of PE was first performed in 1893 using surgical ligation (7). Over the years, surgical interruption took many forms (ligation, plication, clipping, or stapling), but IVC thrombosis was a frequent complication after these procedures. Endovascular approaches to IVC interruption became a reality in 1967 after the introduction of the Mobin-Uddin filter (8).

Many devices have since been developed for endoluminal caval interruption, and currently there are several devices designed for permanent placement commercially available in the United States. (For detailed information regarding each of these filters, the reader is referred to several reviews [9-12].) Selection of a device requires knowledge of the clinical settings in which filters are used, evaluation of the clot-trapping efficiency of the device, occlusion rate of the IVC and access vein, risk of filter migration, filter embolization, structural integrity of the device, and ease of placement.

Percutaneous caval interruption can be performed either as an outpatient or inpatient procedure. Practically speaking, however, most filter placements will occur in the inpatient population because of ongoing medical therapy for acute thromboembolic disease or underlying illness.

The IVC should be assessed with imaging prior to placement of a filter, and the current preferred method is by vena cavography. Prior to filter selection and placement, the infrarenal IVC length and diameter should be measured, the location and number of renal veins determined, IVC anomalies defined (e.g., duplication), and intrinsic IVC disease such as pre-existing thrombus or extrinsic compression excluded. The ideal placement for the prevention of lower extremity and pelvic venous thromboembolism is the infrarenal IVC. The apex or superior aspect of any filtration device should be at or immediately inferior to the level of the renal veins according to the manufacturer's recommendations. In specific clinical circumstances other target locations may be appropriate.

Percutaneous caval interruption is commonly accomplished through right femoral or right internal jugular vein approaches; however, other peripheral and central venous access sites can be used. Filters can be placed in veins other than the vena cava to prevent thromboembolism. Implant sites have included iliac veins, subclavian veins, superior vena cava, and inferior vena cava (suprarenal and infrarenal). This paper will provide quality improvement guidelines for filter placement within the inferior vena cava because of the limited data available for implantation sites other than the IVC. The patient's clinical condition, the type of filter available, the alternative access sites available, and the expertise of the treating physician should always be considered when the decision to place an IVC filter has been made.

These guidelines are written to be used in quality improvement programs to assess percutaneous interruption of the IVC to prevent pulmonary embolism. The most important aspects of care are 1) patient selection, 2) performing the procedure, and 3) monitoring the patient. The outcome measures or indicators for these

processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

II. DEFINITIONS (13, 17)

For the purpose of this standard, the following definitions apply:

Procedural success - deployment of a filter such that the filter is judged suitable for mechanical protection against PE.

Procedural failure - the procedure concludes with unsatisfactory filter deployment such that the patient has inadequate mechanical protection against PE.

Death - death directly attributable to the filter placement, documented by clinical findings, imaging, or autopsy.

Recurrent PE - pulmonary embolism occurring after filter placement and documented by pulmonary arteriography, cross sectional imaging, or significant change in ventilation/perfusion (V/Q) lung scan indicative of recurrent PE, or autopsy.

IVC occlusion - presence of an occluding thrombus in the IVC occurring after filter insertion and documented by ultrasound, CT, MRI, venography, or autopsy.

IVC penetration - penetration of the vein wall by filter hooks with transmural incorporation. For quality improvement reporting purposes, the definition of IVC penetration is filter strut or anchor devices extending more than 3 mm outside the wall of the IVC as demonstrated by CT, ultrasound, venography, or autopsy. Acute penetration occurring during placement of the filter is considered an insertion problem (see below).

Filter embolization - post-deployment movement of the filter to a distant anatomic site completely out of the target zone.

Filter migration - a change in filter position compared to its deployed position (either cranial or caudal) more than 2 cm as documented by plain film imaging, CT, or venography.

Filter fracture - any loss of structural integrity (i.e., breakage or separation) of the filter documented by imaging or autopsy.

Insertion problems - filter or deployment system related malfunctions such as incomplete filter opening, filter tilt more than 15° from the IVC axis (e.g., non-self-centering filters), misplacement of filter outside the infrarenal IVC when the operator's intent is to place the filter in the infrarenal IVC (e.g., when a portion of the filter is within one iliac vein), or prolapse of filter components. Filter malposition requiring surgical removal is considered an insertion problem complication.

Access site thrombus - occlusive or nonocclusive thrombus developing after filter insertion at the venotomy site.

Other access site complications with clinical sequelae - arteriovenous fistula, hematoma, or bleeding requiring a transfusion, hospitalization (either admission or extended stay), or further treatment for management.

III. INDICATIONS (13-16)

A. Accepted

1. Patients with evidence of pulmonary embolus or IVC, iliac, or femoral-popliteal DVT and one or more of the following:

- a. Contraindication to anticoagulation
- b. Complication of anticoagulation
- c. Failure of anticoagulation

- i. Recurrent PE despite adequate therapy.
 - ii. Inability to achieve adequate anticoagulation.
2. Massive pulmonary embolism with residual deepvenous thrombus in a patient at risk for further PE.
3. Free floating iliofemoral or inferior vena cava thrombus.
4. Severe cardiopulmonary disease and deep-vein thrombosis (DVT) (e.g., cor pulmonale with pulmonary hypertension).
5. Poor compliance with anticoagulant medications.

B. Additional Indications for Selected Patients

1. Severe trauma without documented PE or DVT.
 - a. Closed head injury
 - b. Spinal cord injury
 - c. Multiple long bone or pelvic fractures
2. High-risk patients (e.g., immobilized, ICU patients, prophylactic pre-operative placement in patients with multiple risk factors for venous thromboembolism).
3. For pediatric and young adult patients, filter placement indications should be strict, since the long-term effects and durability of the devices are not precisely known.

C. Suprarenal Filter Placement

1. Renal vein thrombosis.
2. IVC thrombosis extending above the renal veins.
3. Filter placement during pregnancy. Suprarenal placement is also appropriate in women of childbearing age.
4. Thrombus extending above previously placed infrarenal filter.
5. Pulmonary embolism following gonadal vein thrombosis.
6. Anatomic variants: duplicated IVC, low insertion of renal veins.

The threshold for these indications is 95%. When fewer than 95% of procedures are performed for these indications, the process of patient selection will be reviewed according to institutional policy.

IV. RELATIVE CONTRAINDICATIONS

- A. Uncorrectable Severe Coagulopathy
- B. Bacteremia or Untreated Infection

Clinical judgment should be applied in these situations, weighing the theoretical risk of implant infection versus the risk of pulmonary embolism.

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

Physicians involved in the performance, supervision and interpretation of IVC filter placement procedures should be Diagnostic Radiologists and must have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec. Also acceptable are foreign Specialist qualifications if the Radiologist so qualified holds an appointment in Radiology with a Canadian University.

As new imaging modalities and interventional techniques are developed additional clinical training, under supervision and with proper documentation, should be obtained before radiologists interpret or perform such examinations or procedures independently. Such additional training must meet with pertinent provincial/regional regulations. Continuing professional development must meet with the requirements of the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.

B. Radiologic Technologist

1. The medical radiation technologist must have Canadian Association of Medical Radiation Technologists certification or be certified by an equivalent licensing body recognized by the CAMRT. Under the overall supervision of the radiologists, the technologist will have the responsibility for patient comfort and safety, for examination preparation and performance, and for image technical evaluation and quality and applicable quality assurance.

The training of technologists engaged in specialty activities shall meet with applicable and valid national and provincial specialty qualifications. Continued education of technologists is encouraged by the C.A.M.R.T. and should meet pertinent provincial regulations.

2. The technologist, together with the physician and nursing personnel, should have responsibility for patient comfort. The technologist should be able to prepare and position the patient for the percutaneous filter placement procedure and together with the nurse, monitor the patient during the examination. The technologist should obtain the imaging data in a manner prescribed by the supervising physician.

C. Nursing Services

Nursing services are an integral part of the team for pre- and postprocedure patient management and education and are recommended in monitoring the patient during the procedure.

VI. SPECIFICATIONS OF THE EXAMINATION

Several technical requirements are necessary to ensure safe and successful percutaneous filter placement procedures. These include adequate arteriographic equipment and institutional facilities, physiologic monitoring equipment, and support personnel.

A. Equipment and Facilities for Percutaneous Filter Placement

The following are considered the minimum equipment requirements for performing vena cavagram(s) and percutaneous filter placement. In planning facilities for percutaneous IVC placement, equipment and facilities more advanced than those outlined below may be desired to produce higher quality studies with reduced risk and time of study. In general, the facility should include at a minimum:

1. A high-resolution image intensifier and television chain with standard angiographic filming capabilities including serial 14-inch film changers, and/or large format image intensifiers (12-inch or greater) with minimum 1024 image matrix. Digital angiographic systems are recommended, as they allow for reduced volumes of contrast material and reduced examination times. Images are acquired and stored either on conventional film or digitally on computerized storage media. Imaging and image recording must be consistent with the as low as reasonably achievable (ALARA) radiation safety guidelines. The use of cineradiography or small field mobile image intensifiers is inappropriate for the routine recording of the venacavagram and percutaneous IVC placement, because these methods have an unacceptably high patient and operator radiation dose.

2. Adequate angiographic supplies such as catheters, guidewires, needles, and introducer sheaths.
3. An angiographic injector capable of varying injection volumes and rates with appropriate safety mechanisms to prevent overinjection.
4. An angiography suite that is large enough to allow easy transfer of the patient from the bed to the table and allow room for the procedure table, monitoring equipment, and other hardware such as intravenous pumps, respirators, anesthesia equipment, and oxygen tanks. Ideally, there should be adequate space for the operating team to work unencumbered on either side of the patient and for the circulation of other technical staff in the room without contaminating the sterile conditions.
5. An area within the institution appropriate for patient preparation prior to the procedure and for observation of patients after the procedure. This might be within the radiology department, in a shortstay unit, or in a routine nursing unit. At this location, there should be personnel to provide care as outlined below (Patient Care), and there should be immediate access to emergency resuscitation equipment.

B. Physiologic Monitoring and Resuscitation Equipment

1. Sufficient equipment should be present in the procedure suite to allow for monitoring the patient's heart rate, cardiac rhythm, and blood pressure. For facilities utilizing conscious sedation, a pulse oximeter monitor should be available.
2. There should be ready access to equipment and drugs for emergency resuscitation. The equipment should include an emergency defibrillator with paper recorder and quick-view capability, oxygen supply and appropriate tubing and delivery systems, suction equipment, tubes for endotracheal intubation, laryngoscope, ventilation bag- askvalve apparatus, and central venous line sets. Drugs for treating cardiopulmonary arrest, contrast reaction, vasovagal reactions, narcotic or benzodiazepine overdose, bradycardia, and ventricular arrhythmias should also be readily available.

C. Support Personnel

1. Radiologic technologists properly trained in the use of the angiographic equipment should assist in performing and imaging the procedure. They should demonstrate appropriate knowledge of patient positioning, arteriographic image recording, angiographic contrast injectors, angiographic supplies including IVC filters, and the physiologic monitoring equipment.
2. If the patient does not receive conscious sedation, one of the staff assisting the procedure should be assigned to periodically assess the patient's status. If the patient is to undergo conscious sedation, a nurse or other appropriately trained individual should monitor the patient as his/her primary responsibility. This person should maintain a record of the patient's vital signs, time and dose of medications given, and other pertinent information.

D. Surgical support

Although surgical or other emergency treatment is needed infrequently for serious complications after percutaneous filter placement procedures, there should be prompt access to surgical and interventional equipment and specialists familiar with the management of patients with complications in the unlikely event of a life- hreatening complication.

E. Patient Care

1. Preprocedure care

For elective percutaneous filter placement, the following should be documented:

- a. Clinically significant history, including indications for the procedure.
- b. Clinically significant physical examination, including an awareness of clinical or medical

conditions that may necessitate specific care.

c. Clinically indicated laboratory evaluation including, but not limited to, coagulation factors, creatinine, and white blood cell count.

Informed consent is recommended for these procedures.

For emergency procedures, a note should be written summarizing the indication for the study, the pertinent history and physical findings, if available, and the proposed procedure.

2. Procedural care

a. All patients should have cardiac monitoring continuously during the procedure with intermittent blood pressure monitoring. A record of vital signs should be maintained.

b. All patients should have intravenous access for the administration of fluids and medications as needed.

c. If the patient is to receive conscious sedation, pulse oximetry should be used. A registered nurse or other appropriately trained personnel should be present, and his/her primary responsibility should be to monitor the patient. A record should be kept of medication doses and times of administration.

3. Postprocedure care

a. A procedure note should be written in the patient's chart summarizing the major findings of the study and any immediate complications. This note may be brief if a formal report will be available within a few hours. However, if the typed report is not likely to be on the chart the same day, a more detailed summary of the study should be written in the chart at the conclusion of the procedure. For outpatients a dictated report is sufficient. In all cases, pertinent findings should be communicated to the referring physician in a timely manner.

b. All patients should be at bed rest and observed in the initial postprocedure period. The length of this period of bed rest will depend on the site and size of the venotomy and the patient's medical condition.

c. During the initial postprocedure period, skilled nurses or other appropriately trained personnel should periodically monitor the puncture site.

d. Initial ambulation of the patient must be carefully supervised. The puncture site stability and independent patient function and mobility must be assured.

e. The operating physician or a qualified designee should evaluate the patient after the procedure, and these findings should be summarized in a progress note. If conscious sedation was administered prior to and during the procedure, complete recovery from conscious sedation must be documented. The physician or designee should be available for continuing care during hospitalization and after discharge. The designee may be another physician or a nurse.

F. Selection Criteria for Short-Term Observation

The duration of postprocedure observation must be individualized. Percutaneous IVC filter placement can be performed on some patients with a short period of postprocedure observation (less than 6 hours) prior to discharge to home; others require overnight care.

VII. QUALITY IMPROVEMENT

A. Success Rates and Thresholds

While practicing physicians should strive to achieve perfect outcomes (e.g., 100% success, 0% complications), in practice all physicians will fall short of this ideal to a variable extent. Thus indicator thresholds may be used to assess the efficacy of ongoing improvement programs. For the purpose of these guidelines, a threshold is a specific level of an indicator that should prompt a review. Individual complications may also be associated with complicationspecific thresholds. When measures such as indications or success rates fall below a minimum threshold, or when complication rates exceed a maximum threshold, a review should be performed to determine causes and to implement changes, if necessary. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Thus, setting universal thresholds is very difficult, and each department is urged to alter

the thresholds as needed to higher or lower values, to meet its own quality improvement program needs.

Complications can be stratified on the basis of outcome. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight). (see Appendix A.) The complication rates and thresholds below refer to major complications.

It is expected that the technical success for percutaneously placed inferior vena cava filters will be 97% or better in experienced hands. Therefore, the proposed threshold for review of technical failures should be 3%.

B. Complication Rates and Thresholds

1. Complications

Each currently available filter has been extensively studied as part of the FDA approval process. Few comparative studies have been completed evaluating all filters in one project, and those that have done so have been retrospective analyses. Complication rates are highly variable depending on the filter being studied. For simplicity, these guidelines do not suggest threshold rates for each individual filter, rather filtration devices are considered as a group.

TABLE 1

Complications	Reported Rates (%)	Threshold (%)
Death (7)	0.12	<1
Recurrent PE (17-22)	0.5-6	5
IVC occlusion (11, 17, 19, 20, 23-27)	2-30	10
Filter embolization (17, 24, 40-49)	2-5	2
Access site thrombosis - major (see Appendix A) (36, 52)	0-6*	1

*Includes reported rates of both major and minor complications.

Published rates for individual types of complications are highly dependent on patient selection and are in some cases based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. It is also recognized that a single complication can cause a rate to cross above a complicationspecific threshold when the complication occurs in a small volume of patients (e.g., early in a quality improvement program).

2. Other Trackable Events

Because an IVC filter is a permanent implantable device and is sometimes placed in relatively young patients, several other trackable parameters when observed are appropriate to record in a quality improvement program. The following events may or may not be clinically significant in a particular patient. For this reason, thresholds for these events are not included in this document.

TABLE 2

Other Trackable Events	Reported Rates (%)
IVC penetration *(7, 17, 19, 23, 27, 28, 39)	0-41
Filter migration *(7, 9, 10, 17, 19-21, 26, 29)	0-18
Filter fracture (17, 24)	2-10
Access site thrombus:	
All types (7, 30, 36, 37)	
Occlusive (35, 36)	0-25
3-10	
Insertion problems (7, 17, 19-22, 24, 26, 30-32)	5-50
Other complications (33, 4)	1-15

*Clinically significant penetration and migration are felt to be rare. The rate of clinically significant penetration is undefined in the literature (39, 50, 51).

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Appendix A

Society of Cardiovascular and Interventional Radiology Standards of Practice Committee
Classification of Complications by Outcome

Minor Complications

- A. No therapy, no consequence.
- B. Nominal therapy, no consequence; includes overnight admission for observation only.

Major Complications

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