



Quality Improvement Guidelines for the Performance of Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism

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ABBREVIATIONS

DVT = deep vein thrombosis, IVC = inferior vena cava, PE = pulmonary embolism

PREAMBLE

The membership of the Society of Interventional Radiology (SIR) Standards of Practice Committee represents experts in a broad spectrum of interventional procedures from both the private and academic sectors of medicine. Generally Standards of Practice Committee members dedicate the vast majority of their professional time to performing interventional procedures; as such they represent a valid broad expert constituency of the subject matter under consideration for standards production.

Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of this document are available upon request from SIR, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033.

METHODOLOGY

SIR produces its Standards of Practice documents using the following process. Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. A recognized expert is identified to serve as the principal author for the standard. Additional authors may be assigned dependent upon the magnitude of the project.

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S.P.K. receives royalties from book publishers Amirsys and Elsevier. W.E.A.S. is a paid consultant for Boston Scientific (Natick, Massachusetts), has research funded by Siemens (Forchheim, Germany), and serves on the Speaker's Bureau for Atrium (Hudson, New Hampshire). None of the other authors have identified a conflict of interest

The initial version of this article first appeared in *JVIR* 2003; 14:S271–S275.

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J Vasc Interv Radiol 2011; 22:1499–1506

DOI: 10.1016/j.jvir.2011.07.012

An in-depth literature search is performed by using electronic medical literature databases. Then, a critical review of peer-reviewed articles is performed with regard to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it contains evidence-based data with respect to content, rates, and thresholds.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members by using a Modified Delphi Consensus Method (Appendix A). For purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Revisions Subcommittee members of the Standards of Practice Committee, either by telephone conference calling or face-to-face meeting. The finalized draft from the Committee is sent to the SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Subcommittee, and appropriate revisions made to create the finished standards document. Before its publication, the document is endorsed by the SIR Executive Council.

INTRODUCTION

This guideline was revised by the American College of Radiology (ACR) in collaboration with SIR.

These guidelines are written to be used in quality improvement programs to assess inferior vena cava (IVC) filter placement procedures. The most important processes of care are (i) patient selection, (ii) performing the procedure, and (iii) monitoring the patient. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

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 to 200,000 fatalities per year are directly attributable to PE (1–4). The current preferred treatment for deep vein thrombosis (DVT) and PE is anticoagulation. However, as many as 20% of these patients will have recurrent PE despite adequate anticoagulation (3,5,6).

Interruption of the IVC for the prevention of PE was first performed in 1893 by 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 several devices designed for permanent placements are commercially available in the United States. In addition to

permanent IVC filters, retrievable IVC filters are also available. These filters can be left in place as a permanent implant but also can be removed when the indication for filter placement resolves. (Detailed information regarding each of these filters can be found in several reviews [9–23].) Selection of a device requires knowledge of the clinical settings in which filters are used, as well as an evaluation of the clot-trapping efficiency and structural integrity of the device, the occlusion rate of the IVC and access vein, the risk of filter movement and filter embolization, magnetic resonance (MR) imaging compatibility of the device, and the ease of placement.

Placement of a caval filter can be performed 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 before placement of a filter, and the current preferred method is by vena cavography. Before filter selection and placement, the length and diameter of the infrarenal IVC should be assessed, the location and number of renal veins determined, IVC anomalies defined (eg, duplication), and intrinsic IVC disease such as preexisting thrombus or extrinsic compression excluded. If available, earlier imaging studies (eg, contrast-enhanced computed tomography [CT] or MR imaging of the abdomen) may be used to evaluate the anatomy of the IVC (ie, size, patency, and anatomic variants). The ideal location for filter placement for preventing 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.

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

IVC filters labeled as retrievable by the United States Food and Drug Administration are also labeled for permanent placement. Retrievable filters may be placed with the intent of either temporary or permanent filtration. Removal of retrievable IVC filters may be accomplished in those cases in which the indication was for prophylaxis and prevention of PE with temporary contraindication to anticoagulation. Filters placed with the intent of subsequent retrieval may be left in place permanently for any of several reasons (eg, continuing need for filtration, thrombus on the filter, inability to retrieve the filter). Data for the feasibility of filter retrieval vary widely among devices and centers. Filters that are not retrieved function as permanent filters.

Definitions

For the purpose of this guideline, the following definitions apply (24,25):

Permanent placement. Permanent placement is deployment in those situations in which lifelong protection against thromboembolic episodes is needed.

Temporary placement. Temporary placement is deployment in those situations in which time-limited protection against thromboembolic episodes is needed.

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

Recurrent PE. Recurrent PE is PE that occurs after filter placement and is documented by pulmonary arteriography, cross-sectional imaging, or

significant change in ventilation/perfusion lung scan indicative of recurrent PE, or at autopsy.

IVC thrombotic occlusion. IVC thrombotic occlusion is the presence of an occluding thrombus in the IVC after filter insertion and documented by ultrasound (US), CT, MR imaging, venography, or autopsy; this may be symptomatic or asymptomatic.

IVC penetration. IVC penetration is penetration of the vein wall by a filter strut or anchor device 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 or venography, or at autopsy. Acute penetration occurring during placement of the filter is considered an insertion problem (as detailed later).

Filter embolization. Filter embolization is postdeployment movement of the filter or its components to a distant anatomic site completely out of the target zone.

Filter movement. Filter movement is a change in filter position compared with its deployed position (cranial or caudal) of more than 2 cm as documented by plain radiography, CT, or venography.

Filter fracture. Filter fracture is any loss of a filter's structural integrity (ie, breakage or separation) documented by imaging or at autopsy.

Insertion problems. Insertion problems refer to malfunctions of the filter or deployment system such as incomplete filter opening, filter tilt more than 15° from the IVC axis (eg, 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 (eg, when a portion of the filter is within one iliac vein), or prolapse of filter components. Filter malposition requiring surgical/endovascular removal is considered an insertion problem complication.

Access site thrombus. Access site thrombus refers to occlusive or nonocclusive thrombus developing at the venotomy site after filter insertion, and documented by US or other imaging.

Access site complications with clinical sequelae. Access site complications with clinical sequelae include arteriovenous fistula, hematoma, or bleeding requiring a transfusion, hospitalization (admission or extended stay), or further treatment.

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; Appendix B). The complication rates and thresholds herein refer to major complications unless otherwise specified.

INDICATIONS

Therapeutic (Documented Thromboembolic Disease)

IVC filter placement has a therapeutic indication (ie, in cases of documented thromboembolic disease) in patients with evidence of PE or IVC, iliac, or femoropopliteal DVT and one or more of the following:

- Absolute or relative contraindication to anticoagulation;
- Complication of anticoagulation;
- Failure of anticoagulation;
- Recurrent PE despite adequate therapy;
- Inability to achieve/maintain adequate anticoagulation;
- Propagation/progression of DVT during therapeutic anticoagulation;
- Massive PE with residual DVT in a patient at risk for further PE;
- Free-floating iliofemoral or IVC thrombus; and

- Severe cardiopulmonary disease and DVT (eg, cor pulmonale with pulmonary hypertension) (24–31).

Prophylactic (No Current Thromboembolic Disease)

IVC filter placement has a prophylactic indication (ie, in cases without current thromboembolic disease) in the following settings:

- Severe trauma without documented PE or DVT;
- Closed head injury;
- Spinal cord injury;
- Multiple long-bone or pelvic fractures; and
- Patients at high risk (eg, immobilized or in an intensive care unit) (24–31).

Suprarenal Filter Placement

Suprarenal caval filter placement may be considered when any of the following situations exist in addition to the indications listed earlier.

1. Presence of IVC thrombus precluding placement of a filter in the infrarenal IVC;
2. Filter placement during pregnancy (suprarenal placement is also appropriate in women of childbearing age);
3. Thrombus extending above previously placed infrarenal filter;
4. Gonadal vein thrombosis;
5. Anatomic variants, eg, duplication of the IVC, low insertion of renal veins;
6. Significant extrinsic compression of the infrarenal IVC;
7. Intrinsic narrowing of the infrarenal IVC; and
8. Intraabdominal or pelvic mass in patients who will undergo surgery and in whom operative IVC mobilization is contemplated.

The IVC should be assessed with imaging before placement of a filter. The current preferred method is by vena cavography. Before filter selection and placement, the length and diameter of the suprarenal IVC should be assessed, the location and number of renal veins determined, the location and number of hepatic veins determined, the right atrium identified, IVC anomalies (eg, duplication) defined, and intrinsic IVC disease, such as preexisting thrombus or extrinsic compression, excluded. If available, previous imaging studies (eg, contrast-enhanced CT or MR imaging of the abdomen) may be used to evaluate the anatomy of the IVC (ie, size, patency, and anatomic variants). The anatomic considerations should be used in the final planning for filter placement and choice of device.

Filters Placed for Temporary Use and Possible Future Retrieval

Placement of filters for temporary use and possible future retrieval may be considered when any of the following situations exist in addition to the indications listed earlier.

1. PE and/or DVT and transient inability to anticoagulate;
2. Prophylactic prevention of PE in patients at high risk; and
3. The use of retrievable filters should also be considered in pediatric and young adult patients, as the long-term effects and durability of the devices are not precisely known. Currently, there are no filters specifically designed for use in children. The safety and efficacy of vena cava filters in children have not been firmly established. Case reports and series have described the placement and removal of filters in children, but their long-term effect is unclear (32).

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

RELATIVE CONTRAINDICATIONS

Relative contraindications to IVC filter placement in this setting are (i) uncorrectable severe coagulopathy and (ii) bacteremia or untreated infec-

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

SPECIFICATIONS OF THE EXAMINATION

There are several technical requirements to ensure safe and successful filter placement procedures. These include adequate angiographic equipment and institutional facilities, physiologic monitoring equipment, and support personnel.

Equipment and Facilities for Filter Placement

The following are considered the minimum equipment requirements for performing vena cavograms and filter placement. In planning facilities for IVC placement, equipment and facilities more advanced than those outlined here may be desired to produce higher-quality studies with reduced risk and time of study.

The facility should include, at a minimum:

1. A high-resolution image receptor, preferably with a 28–40-cm field of view, and an imaging chain with standard angiographic filming capabilities including serial 14-inch film changers or (preferably) a digital imaging system with a minimum 1,024-image matrix. Digital angiographic systems are preferred, as they allow for reduced volumes of contrast material and reduced examination times. Images are acquired and stored on conventional film or digitally on computerized storage media. Imaging and image recording must be consistent with the “As Low As Reasonably Achievable” radiation safety guidelines. The use of cineradiography or small-field mobile image intensifiers is inappropriate for the routine recording of the vena cavogram and IVC placement, because these methods cause an unacceptably high patient and operator radiation dose. Use of last image-hold and pulsed fluoroscopy are recommended for dose reduction;
2. Adequate angiographic supplies such as catheters, guide wires, 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; and
5. An area within the institution appropriate for patient preparation before the procedure and for observation of patients after the procedure. This might be within the radiology department, a short-stay unit, a routine nursing unit, or a postanesthesia care unit. At this location, there should be personnel to provide care as outlined later in the Patient Care section, and there should be immediate access to emergency resuscitation equipment.

Physiologic Monitoring and Resuscitation Equipment

1. Equipment should be present in the procedure suite to allow for monitoring the patient’s heart rate, cardiac rhythm, and blood pressure. For facilities that use moderate sedation, a pulse oximeter monitor should be available, as outlined in the Practice Guideline for Sedation/Analgesia (33).
2. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications and/or procedural complications. The equipment should be maintained and medications inventoried for drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

Support Personnel

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, angiographic image recording, angiographic contrast agent injectors, angiographic supplies including IVC filters, and the physiologic monitoring equipment. Certification as a vascular and interventional radiologic technologist is one measure of appropriate training. The technologist should be trained in basic cardiopulmonary resuscitation and in the function of the resuscitation equipment.

If the patient does not receive sedation for the procedure, one of the staff assisting the procedure should be assigned to periodically assess the patient's status. In cases in which moderate sedation is used in adults, light or moderate sedation is used in children, or the patient is critically ill, an experienced licensed provider should be present whose primary responsibility is monitoring the patient's vital signs, sedation state, and level of comfort/pain. This person should maintain a record of the patient's vital signs, the time and dose of medications given, and other pertinent information, as outlined in the Practice Guideline for Sedation/Analgesia (33).

Acute Care Support

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

Patient Care

For additional information on patient care, see the Practice Guideline for Interventional Clinical Practice (34).

Preprocedure care. For elective filter placement, the following should be documented:

- a. Clinically significant history, including indications for the procedure;
- b. Clinically significant physical or diagnostic examination findings, including clinical or medical conditions that may necessitate specific care, such as preprocedure antibiotics and other measures;
- c. Clinically indicated laboratory evaluation including, but not limited to, coagulation factors, creatinine, white blood cell count, and previously obtained cultures; and
- d. Preprocedure documentation should conform to the requirements of the Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures (35).

Informed consent must be in compliance with all state laws and the ACR Practice Guideline on Informed Consent for Image-Guided Procedures (36).

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.

Procedural care. Adherence to the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery is required for procedures in non-operating room settings, including bedside procedures. "Time out" must be conducted in the location where the procedure will be done, just before starting the procedure and must:

- Involve the entire operative team;
- Use active communication; and
- Be briefly documented, such as in a checklist, and include at least:
 - a. Correct patient identity;
 - b. Correct side and site, if applicable;
 - c. Agreement on the procedure to be done;
 - d. Correct patient position; and
 - e. Availability of correct implants and any special equipment or special requirements

The organization should have processes and systems in place for reconciling differences in staff responses during the time out.

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

signs should be maintained.

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

If the patient is to receive sedation for the procedure, 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. The Practice Guideline for Sedation/Analgesia contains further information (33).

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

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

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

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 before and during the procedure, complete recovery from 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. The Practice Guideline for Sedation/Analgesia contains further recommendations (33).

Selection Criteria for Short-term Observation

The duration of postprocedure observation must be individualized. IVC filter placement can be performed on some patients with a short period of postprocedure observation (< 6 h) before discharge to home; others require overnight care. Short-term observation should only be considered when all the following conditions can be met:

1. Those patients capable of independent ambulation before the procedure demonstrate stable independent ambulation after the procedure. Nonambulatory patients have adequate assistance after discharge to provide care as needed.
2. The patient is capable of following instructions and detecting changes in symptomatology. Alternatively, patients with impaired mental or neurologic status should have adequate assistance after discharge to provide care as needed.
3. The patient is provided with instructions on how to recognize potential complications and how to obtain medical assistance in the event of such complications. A responsible adult is also provided with information regarding recognition of potential complications and is available to transport the patient and be in attendance during the initial night after discharge.
4. The patient is free of concurrent serious medical illness that might contribute to a significantly increased risk of complication.
5. The patient has recovered from the effects of sedation.

Relative Contraindications to Short-term Observation

Several factors must be considered when determining the length of postprocedure skilled nursing care. Some of the relative contraindications to short-term observation are as follows:

1. Patients with significant risk of contrast media-associated nephrotoxicity that might be prevented by hospitalization and intravenous hydration.
2. Patients with coagulopathies or electrolyte abnormalities that require correction should be hospitalized until stable.
3. Insulin-dependent diabetic patients who have labile serum glucose levels in the periprocedural period should be hospitalized until in stable condition.
4. Complications occurring during or after IVC filter placement, including large hematoma, anuria, and persistent nausea and vomiting should prompt observation until symptoms resolve.

5. Patients who exhibit hemodynamic instability or significant dysrhythmia during or after the procedure should be hospitalized until in stable condition.
6. Patients who live alone.
7. Patients with concurrent serious medical illness that might contribute to a significantly increased risk of complication should be hospitalized until in stable condition.
8. Patients with impaired mental or neurologic status who do not have adequate assistance to provide care as needed should be hospitalized until appropriate assistance is available or no longer required.

The decision for short-term or longer-term postprocedure observation must be individualized, and a patient's care may vary from the aforementioned criteria for sound clinical reasons. The decision in each case must be made by the physician who performed the procedure and the referring physician after review of all pertinent data.

DOCUMENTATION

Reporting should be in accordance with the Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures (35).

RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This concept is known as As Low As Reasonably Achievable.

Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with As Low As Reasonably Achievable, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index, or lateral width. The dose reduction devices that are available on imaging equipment should be active or manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Periodically, radiation exposures should be measured and patient radiation doses estimated by a medical physicist in accordance with the appropriate ACR Technical Standard (ACR Resolution 17, adopted in 2006, revised in 2009, resolution 11).

QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading "Position Statement on Quality Control and Improvement, Safety, Infection Control, and Patient Education" on the ACR Web page (<http://www.acr.org/guidelines>).

These data should be used in conjunction with the thresholds described in the subsequent section to assess filter placement procedural efficacy and complication rates, and to trigger institutional review when these thresholds are exceeded.

QUALITY IMPROVEMENT

Success Rates and Thresholds

Although practicing physicians should strive to achieve perfect outcomes (eg, 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 complication-specific thresholds. When measures such as

Table 1. Reported Rates and Thresholds for Complications (7,24,37–54)

Complication	Reported Rate (%)	Threshold (%)
Death (7)	0.12	<1
Filter embolization (24,37–49)	0.1	1
Deployment outside target area (50–52)	1–9	0
Access site thrombosis/occlusion (53,54)	3–10	3

Table 2. Reported Incidences of Trackable Adverse Events (2,7,10,12,13,24,43,53,55–72)

Event	Reported Rate (%)
IVC penetration*(7,24,55–59)	0–41
Filter movement*(7,10,12,24,56,60–63)	0–18
Filter fracture (24,43)	2–10
Recurrent PE (24,56,61,53–65)	0.5–6
Access site thrombus, all types (7,53,64,65)	0–25
IVC occlusion (13,24,42,55,56,59,62,63,68)	2–30
Insertion problems (7,24,43,56,51–63,65,67,69,70)	5–23
Other complications (2,71,72)	1–15

* Clinically significant penetration and movement are believed to be rare. The rate of clinically significant penetration has been reported to be 0.4% (72), but is not precisely defined in the literature.

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. Therefore, 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.

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

Participation by the radiologist in patient follow-up is an integral part and will increase the success rate of the procedure. Close follow-up, with monitoring and management of patients who have undergone placement of IVC filters is appropriate for the radiologist.

Complication Rates and Thresholds

Complications. Each currently available filter has been extensively studied as part of the Food and Drug Administration approval process. Few comparative studies have been completed to evaluate 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) (7,24,37–54).

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 complication-specific threshold when the complication occurs within a small patient volume (eg, early in a quality improvement program).

Other trackable events. Because an IVC filter may be implanted as a permanent device (if not retrieved) and can be used in relatively young patients, several other trackable parameters when observed are appropriate to record in a quality improvement program. The events listed in **Table 2** (2,7,10,12,13,24,43,53,55–72) may or may not be clinically significant in a particular patient. For this reason, thresholds for these events are not included in this document.

ACKNOWLEDGMENTS

Drew M. Caplin, MD, authored the first draft of this document and served as topic leader during the subsequent revisions of the draft. Wael E.A. Saad, MD, is chair of the SIR Standards of Practice Committee. Boris Nikolic, MD, MBA, is chair of the Revisions Subcommittee. Dr. Sanjoy Kundu served as SIR Standards Division Councilor during the development of this document and contributed to its content. All other authors are listed alphabetically. Other members of the Standards of Practice Committee and SIR who participated in the development of this clinical practice guideline are (listed alphabetically): John “Fritz” Angle, MD, Daniel B. Brown, MD, Danny Chan, MD, Sean R. Dariushia, MD, Jon C. Davidson, MD, B. Janne d’Othee, MD, MPH, Maxim Itkin, MD, Arshad Ahmed Khan, MD, Hyun S. Kim, MD, Gloria M. Martinez-Salazar, MD, Darren Postoak, MD, Tarun Sabharwal, MD, Cindy Kaiser Saiter, NP, Marc S. Schwartzberg, MD, Samir S. Shah, MD, Nasir H. Siddiqi, MD, Constantinos T. Sofocleous, MD, PhD, LeAnn Stokes, MD, Rajeev Suri, MD, Timothy L. Swan, MD, Patricia E. Thorpe, MD, Richard Towbin, MD, Aradhana Venkatesan, MD, Michael J. Wallace, MD, and Joan Wojak, MD.

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APPENDIX A: SIR STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

- A. Require no therapy, result in no consequence.
- B. Require nominal therapy, result in no consequence; includes overnight admission (≥ 23 h) for observation only.

Major Complications

- C. Require therapy, minor hospitalization (≥ 24 h but < 48 h).
- D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 h).
- E. Result in permanent adverse sequelae.
- F. Result in death.

APPENDIX B: CONSENSUS METHODOLOGY

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from Standards of Practice Committee members' practices, and, when available, the SIR HI-IQ System national database.

Consensus on statements in this document was obtained utilizing a modified Delphi technique (1,2).

The Committee was unable to reach consensus on the following:

1. Indication, efficacy, or complication threshold.
2. Indication, efficacy, or complication threshold.

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SIR DISCLAIMER

SIR Disclaimer The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed towards the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.