CIRSE Office Vienna, Neutorgasse 9/4a, 1010 Vienna, Austria
P +43 1 904 2003, F +43 1 904 2003 30, info@cirse.org, www.cirse.org

QUALITY IMPROVEMENT GUIDELINES FOR PERCUTANEOUS INFERIOR VENA CAVA FILTER PLACEMENT FOR THE PREVENTION OF PULMONARY EMBOLISM

European Standards adopted and modified by CIRSE in cooperation with SCVIR Standards of Practice Committee
This document was adapted for CIRSE by Professor Jim A. Reekers
The document was reviewed for CIRSE by Professor Martin Zwaan and Dr Ferenc Szatmári
The CIRSE Officer for Standards of Practice is Dr Mario Bezzi
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Introduction

Pulmonary embolism (PE) continues to be a major cause of morbidity and mortality. Estimates of the incidence of non-fatal PE range from 400,000-630,000 cases per year and 50,000-200,000 fatalities per year directly attributable to PE.[1,2,3,4] 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. These devices are designed for permanent placement. For detailed information regarding each of these filters, the reader is referred to several reviews.[9,10,11,12] 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 embolisation, 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 manufacturers recommendations. In specific clinical circumstances, other target locations may be appropriate.

Percutaneous caval interruption is commonly accomplished through right femoral and 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 programmes to assess percutaneous interruption of the IVC to prevent pulmonary embolism. The most important processes 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.

Definitions[13,17]

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 - Procedurally related death directly attributable to the filter itself documented by clinical findings, imaging, or autopsy.

Recurrent PE - Pulmonary embolism occurring after filter placement documented by pulmonary arteriography, cross sectional imaging, altered ventilation-perfusion (V/Q) lung scan to high probability of 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 demonstrated by CT, ultrasound, venography, or autopsy. Acute penetration occurring during placement of the filter is considered an insertion problem (see below).

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

Migration - Filter migration defined as 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 centring filters), misplacement of filter outside of the infrarenal IVC when the operators' 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 non-occlusive thrombus developing after filter insertion at the venotomy site.

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

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 quality improvement programmes. 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 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 programme 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 hospitalisation, 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.

Indications[13,14,15,16]

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

Additional indications for selected patients:

1. Massive pulmonary embolism with residual deep venous thrombus in a patient at risk of further PE
2. Free floating iliofemoral or inferior vena cava thrombus
3. Severe cardiopulmonary disease and DVT (e.g. cor pulmonale with pulmonary hypertension)
4. Poor compliance with anticoagulant medications
5. Severe trauma without documented PE or DVT
    a. Closed head injury
    b. Spinal cord injury
    c. Multiple long bone or pelvic fractures
6. High risk patients (e.g. immobilised, ICU patients, prophylactic pre-operative placement in patients with multiple risk factors of venous thromboembolism)

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

1. Uncorrectable severe coagulopathy (e.g. patients with liver or multisystem failure)
2. Caution should be exercised when placing a filter in patients with bacteraemia or untreated infection; clinical judgement should be applied in these situations weighing the theoretical risk implant infection versus the risk of pulmonary embolism

For paediatric and young adults patients filter placement indications should be strict, since the long-term effects and durability of the devices are not precisely known.
The threshold for these indications is 95%. When fewer than 95% of procedures are performed for these indications, the department will review the process of patient selection.

Success

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%.

Complications

Every 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 will not suggest threshold rates for each individual filter, rather filtration devices will be 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 Embolisation[17,24,40-49]	2-5	2
Access Site Thrombosis - Major (see Appendix A)[36,52]	0-6*	1

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 recognised that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs in a small volume of patients, e.g. early in a quality improvement programme.

Other Trackable Events

Because an IVC filter is a permanent implantable device and because this device is sometimes placed in relatively young patients, several other trackable parameters, when observed, are appropriate to record in a quality improvement programme. 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
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]	0-25
Occlusive[35,36]	3-10
Insertion Problems[7,17,19-22,24,26,30-32]	5-50
Other complications[33,34]	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]

CIRSE clinical practice guidelines 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. 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.

TEMPORARY VENA CAVA FILTERS

Temporary vena cava filters are available in Europe but not in the US. This part of the document is therefore unrelated to SCVIR

Introduction

Implantation in the inferior vena cava (IVC) of a permanent vena cava filter (PVCF) can be regarded as a therapy modality for the prevention of pulmonary embolism (PE) in the management of venous thromboembolic disease. However, a number of recent papers have reported on the efficacy and the relatively high complication rate of different types of permanent IVC filters. Long-term follow-up by Ferris et al (Radiology 1993; 188:851-865) of 320 patients with 7 different types of PVCF revealed an IVC thrombosis in 19%.

The IVC wall penetration of >3mm in 9%, PE with a filter in place in 10%, filter migration of >1cm in 6% and filter fractures in 2%. Furthermore, in a recent article by Decoussus et al (ref: NEJM…etc), the authors report that the advantages of a vena cava filter are only in the short term (< 2 years). After this period, the complications associated with the presence of a VCF (e.g. thrombosis) override those of the control group not having a filter. In view of these data, indiscriminate prophylactic use of permanent IVC filters should be avoided. In addition, the data indicates the advantages of being able to remove an IVC filter when the patient is no longer at high risk of PE.

In recent years, filter technology has therefore focused on means to afford temporary protection for those patients with short-term risk of PE (e.g. patients undergoing orthopaedic surgery, patients with temporary contraindication to anticoagulation, patients undergoing thrombolysis for deep venous thrombosis [DVT], and patients whose anticoagulation requires temporary cessation due to surgery). These patients are often young or have an otherwise normal life expectancy.

This has led to the development of temporary tethered filters that must be removed within 2 weeks of insertion and retrievable IVC filters (without tether) that can be retrieved or left in place as permanent filters. The permanent option of the retrievable filter is especially suitable for those patients where uncertainty exists regarding the ethiology of the thrombosis and may in retrospect require permanent partial vena cava interruption.

The clinical advantages of a retrievable filter above a temporary tethered filter are:

1. No risk of infection during the implantation period at the insertion site. Tethered temporary filters (i.e. the filter is attached to a catheter which protrudes outside of the body or is attached under the skin at the insertion site) can become infected at the insertion site;
2. No risk of movement of the filter due to inadvertent manipulation of the filter at the insertion site during the implantation period;
3. The choice to leave the filter in place as a permanent filter should the filter be filled with large amounts of non-resolvable clot;
4. Filters with tethers must always be removed through the introduction (implantation) system and therefore, may require surgical removal in the event of filter thrombosis due to clot capturing;
5. The possibility to leave the filter implanted permanently in case of prolonged risk of PE, without the risk of having to remove the filter and replacing it with a permanent filter.

There is currently only limited commercial availability of retrievable filters in Europe and the countries outside of the USA. None have been approved for use in the USA.

Possible Indications for Temporary or Retrievable Filters:

1. Patients with evidence of pulmonary embolus or IVC, iliac, or femoral-popliteal DVT and temporary contraindication to anticoagulation (e.g. planned surgery)
2. Temporary complication of anticoagulation (e.g. unknown bleeding focus)
3. Massive pulmonary embolism with residual deep venous thrombus in a patient at temporary risk of further PE (e.g. no adequate anticoagulation yet)
4. Local fibrinolysis for DVT
5. Pregnant patient with proven DVT during caesarean section or birth
6. Temporary free floating iliofemoral or inferior vena cava thrombus
7. Severe trauma without documented PE or DVT
   (a) Closed head injury (b) Spinal cord injury (c) Multiple long bone or pelvic fractures
8. High risk patients (e.g. immobilised, ICU patients, prophylactic pre-operative placement in patients with multiple risk factors for venous thromboembolism)

Because the clinical data of placement of a temporary filter is minimal, this should always be balanced against implantation of a permanent filter. Retrievable filters are always preferred above tethered filters. The latter should not be used anymore when a retrievable filter is available.

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APPENDIX A

Society of Cardiovascular & 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 hospitalisation (< 48 hours)
D. Require major therapy, unplanned increase in level of care, prolonged hospitalisation (>48 hours)
E. Permanent adverse sequelae
F. Death

APPENDIX B

Methodology[1]

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 member practices, and, when available, the SCVIR HI-IQ® system national database.

Consensus on statements in this document was obtained utilising a modified Delphi technique ([1,2])

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