Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters

Steven F. Millward, FRCPC, Clement J. Grassi, MD, Thomas B. Kinney, MD, Sanjoy Kundu, MD, Gary J. Becker, MD, John F. Cardella, MD, Louis G. Martin, MD, James E. Silberzweig, MD, and David Sacks, MD, for the Technology Assessment Committee of the Society of Interventional Radiology

J Vasc Interv Radiol 2005; 16:441–443

Abbreviations: DVT = deep vein thrombosis, PE = pulmonary embolism

THIS Standards document is intended as a Supplement to the Recommended Reporting Standards for Vena Cava Filter Placement and Patient Follow-up, published in 1999 (1). Since 1999, there has been increased interest in non-permanent vena cava filters, with both increased research and clinical use of these devices. Several such devices are now approved for use in Europe, Canada, and the United States. The previous Standards did address several issues related specifically to non-permanent filters: this document contains additional issues that have arisen in the interval.

Although there is a large number of publications regarding vena cava filters, the literature is generally limited, with few good prospective studies, and even fewer randomized controlled trials (2). A randomized trial published in 1998 (3) demonstrated the "initial efficacy of filters for the prevention of pulmonary embolism." However, prevention of pulmonary embolism (PE) appeared to be short-lived, and was counterbalanced by an increased risk of recurrent deep-vein thrombosis (DVT) in the patients receiving filters (3). The data published in this trial, which was based on 2-year follow-up, resulted in increased interest in non-permanent filters. Of note, further follow-up data from the same trial showed continued filter protection against PE with no increase in post-thrombotic syndrome at 8 years (4).

PATIENT ASSESSMENT

Data regarding general patient information, the method of diagnosis of DVT or PE, risk factors for thrombosis, and the indications for filter placement, should all be described according to the previous Standards (1). Any additional indications should be specifically addressed, as should any contraindications (5). In addition the protocol must state if the filter was placed with the intention that it would be retrieved, or if it was intended as a permanent filter, or if this was not determined. If filter retrieval was planned the rationale for this should be described: in particular the reasons why the patient may no longer require a filter, and could benefit from filter retrieval should be included.

DEVICE ASSESSMENT

The manufacturer and type of filter should be recorded, along with a description of the delivery system and the technique of placement. The size of the introducer system should be specified. The device should be categorized as either a Temporary Filter or a Retrievable/Optional Filter if possible (6). A Temporary Filter is attached to a wire or catheter that either protrudes from the skin entry site, or may be buried in the adjacent subcutaneous tissues (6,7). Consequently, this type of filter must generally be removed. A Retrievable/Optional Filter is similar to a conventional filter, but it has additional features allowing removal from the body [such as a retrieval hook (6,8,9), a specifically designed removal device (10), or struts/fixation hooks that can be removed from the vena cava wall after endothelialization has occurred (7,10)]. These features should be described. Any drug coat-

From the Department of Diagnostic Imaging (S.F.M.), Peterborough Regional Health Centre, One Hospital Drive, Peterborough, Ontario, Canada and the University of Western Ontario, London, Canada; Department of Radiology (C.J.G.), Lahey Clinic Medical Center, Burlington, MA; UCSD Medical Center (T.B.K.), San Diego, CA; Department of Medical Imaging (S.K.), Scarborough General Hospital, Richmond Hill, Canada; Image-Guided Intervention (G.J.B.), Cancer Imaging Program (NCI), Bethesda, MD; Department of Radiology (J.F.C.), University of Colorado Health Sciences Center, Denver, Colorado; Department of Radiology (L.G.M.), Emory University Hospital, Atlanta, Georgia; St. Luke's Roosevelt Hospital Center (J.E.S.), New York, New York; The Reading Hospital and Medical Center (D.S.), Reading, Pennsylvania. Received and accepted December 21, 2004. **Address correspondence to** S.F.M., Department of Diagnostic Imaging, Peterborough Regional Health Centre, One Hospital Drive, Peterborough, Ontario, K9J 7C6, Canada; E-mail: sfmillward@personainternet.com

DOI: 10.1097/01.RVI.0000156096.22103.18

Reporting Criteria for Filter Retrieval

1. Anticoagulant medications: Specify type and duration of use
2. Implantation period
3. Filters not retrieved: Specify reasons
4. Site of venous access for retrieval
5. Imaging of vena cava prior to retrieval: Include imaging technique, position of filter and trapped emboli
6. Complication or technical difficulty during retrieval: Describe any additional equipment or techniques used
7. Imaging of vena cava following retrieval: Include imaging technique and evidence of vena caval injury

ing, or other technique used to influence incorporation of the device into the vena cava must be described in detail (11).

The reason for device selection should be noted as described in the previous Standards (1). In addition the following points should also be addressed: (i) was the device selected because retrieval/removal was planned? (ii) was a device that was designed to be a permanent filter modified for non-permanent use (12,13)? In a large series where several different devices were used, all data must be collected and reported for each type of filter.

PROCEDURAL ASSESSMENT

This should be described according to the Standards (1).

PLACEMENT PROBLEMS

In addition to the requirements of the previous Standards (1), it should be noted if filter placement was adequate to permit filter retrieval. Any complication should be described as Minor or Major according to the SIR Standards of Practice Committee Classification (5).

FILTER RETRIEVAL/REMOVAL

The results of retrieval must be expressed according to the protocol described in "Patient Assessment," and any changes in the medical condition of the patient, or other factors, that led to a change in the protocol must be described. The removal device should be described. The manufacturer, the size of the system, the type of removal device, and a brief description of the device and the method of use should be included. The requirements under "Procedural Assessment" in the Standards document (1) should be followed, but additional points that must be addressed are listed in the **Table**. All complications should be described and classified as Minor or Major.

With regard to the implantation period, the maximum implantation period of the device according to the manufacturer should be stated. If filters were retrieved after a longer implantation period than is recommended by the manufacturer, this must be stated. Relevant human and/or animal data regarding implantation times should be briefly described. If filter repositioning was undertaken in an attempt to prolong the implantation period (14), the technique and rationale should be described.

In addition to those listed in the Table, the following details should be addressed: (i) were imaging tests used to evaluate the venous system for DVT prior to filter removal? (ii) the position of the filter at the time of retrieval, or on follow-up imaging, should be compared to the position immediately following placement, (iii) if trapped emboli were identified within the filter, or removed with it, this should be documented along with an estimate of the size of the emboli, (iv) any pharmacological or mechanical thrombolytic techniques used to remove trapped emboli should be described, (v) if trapped emboli were removed what measures were taken to prevent and diagnose recurrent PE? (vi) an indication of the amount of force required to retrieve the filter may be included (14), (vii) radiation dose (fluoroscopy time if radiation dose is not available) and the type and dose of contrast agent used should also be recorded (15,16), (viii) if retrieved filters were submitted for histologic or bacteriologic evaluation the results should be reported (17).

FOLLOW-UP ASSESSMENT

The previous Standards document should be followed, both for patients from who filters were retrieved and for those where filters were left in permanently (1). The methods used (both pre- and postfilter retrieval) to diagnose and exclude DVT, PE and chronic venous insufficiency, and the results of these investigations, should be included. If the venous access site used for filter retrieval was evaluated for thrombosis, it is recommended that the results of this imaging be reported. In addition, if placement of a second filter was required the type of filter and the reason for choosing it should be described. Complications should be classified as Minor or Major.

Acknowledgments: Dr. Steven F. Millward authored the first draft of this document and served as topic leaders during the subsequent revisions of the draft. Dr. Clement J. Grassi is chair of the SIR Technology Assessment Committee and Dr. David Sacks is SIR Standards Division Councilor. All other authors are listed alphabetically. Other members of the Technology Assessment Committees who participated in the development of this clinical practice guideline are (listed alphabetically): John Dean Barr, MD, John J. Borsa, MD, Patricia E. Cole, PhD, MD, William B. Crenshaw, MD, Michael D. Dake, MD, Chieh-Min Fan, MD, S. Nahum Goldberg, MD, Ziv Haskal, MD, Randall T. Higashida, MD, Lindsay Machan, MD, Nilesh H. Patel, MD, David A. Phillips, MD, Dheeraj Rajan, MD, John H. Rundback, MD, Curtis W. Bakal, MD, Curtis A. Lewis, MD, and Kenneth S. Rholl, MD.

References

1. Greenfield LJ, Rutherford RB, and the Participants in the Vena Caval Filter Conference. Recommended reporting standards for vena caval filter placement and patient follow-up. J Vasc Interv Radiol 1999; 10:1013–1019.
2. Girard P, Stern JB, Parent F. Medical literature and vena cava filters: so far so weak. Chest 2002; 122:963–927.
3. Decousus H, Leizorovicz A, Parent F, et al. A clinical trial of vena caval filters in the prevention of pulmonary embolism in patients with proximal deep-vein thrombosis. N Engl J Med 1998; 338:409–415.
4. Decousus H. Eight-year follow-up of a randomized trial investigating vena

caval filters in the prevention of PE in patients presenting a proximal DVT: The PREPIC trial. J Thromb Haemost 2003; 1 (suppl 1):OC440.
5. Grassi CJ, Swan TL, Cardella JF, et al. Quality improvement guidelines for percutaneous permanent inferior vena cava filter placement for the prevention of pulmonary embolism. J Vasc Interv Radiol 2001; 12:137–141.
6. Millward SF. Temporary and retrievable inferior vena cava filters: current status. J Vasc Interv Radiol 1998; 9:381–387.
7. Bovyn G, Gory P, Reynaud P, Ricco JB. The Tempofilter: a multicenter study of a new temporary caval filter implantable for up to six weeks. Ann Vasc Surg 1997; 11:520–528.
8. Darcy MD, Smith TP, Hunter DW, Castaneda-Zuniga W, Lund G, Amplatz K. Short-term prophylaxis of pulmonary embolism by using a retrievable vena cava filter. AJR Am J Roentgenol 1986; 147:836–838.
9. Millward SF, Oliva VL, Bell SD, et al. Gunther Tulip retrievable vena cava filter: results from the registry of the Canadian Interventional Radiology Association. J Vasc Interv Radiol 2001; 12:1053–1058.
10. Asch MR. Initial experience in humans with a new retrievable inferior vena cava filter. Radiology 2002; 225: 835–844.
11. De Gregorio MA, Gimeno MJ, Lostale F, et al. Retrievability of uncoated versus Paclitaxel-coated Gunther-Tulip IVC filters in an animal model. J Vasc Interv Radiol 2004; 15:719–726.
12. Cope C, Baum RA, Duszak RA, et al. Temporary use of a Bird's Nest filter during iliocaval thrombolysis. Radiology 1996; 198:765–767.
13. Nutting C, Coldwell D. Use of a TrapEase device as a temporary caval filter. J Vasc Interv Radiol 2001; 12:991–993.
14. De Gregorio MA, Gamboa P, Gimeno MJ, et al. The Gunther Tulip retrievable filter: prolonged temporary filtration by repositioning within the inferior vena cava. J Vasc Interv Radiol 2003; 14:1259–1265.
15. Miller DL, Balter S, Wagner LK, et al. Quality improvement guidelines for recording patient radiation dose in the medical record. J Vasc Interv Radiol 2004; 15:423–429.
16. Omary RA, Bettmann MA, Cardella JF, et al. Quality improvement guidelines for the reporting and archiving of interventional radiology procedures. J Vasc Interv Radiol 2002; 13:879–881.
17. Neeman Z, Auerbach A, Wood BJ. Letter: metastatic involvement of a retrieved inferior vena cava filter. J Vasc Interv Radiol 2003; 14:1585.