Guidelines for the Placement of Vena Cava Filters

University Hospitals of Leicester NHS
NHS Trust
Thrombosis Committee / Imaging service
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1. Introduction / Scope

1.1 The objective of this document is to provide healthcare professionals with guidance on the use and management of inferior vena cava (IVC) filters. The sole function of vena cava filters is to prevent clinically significant pulmonary embolism (PE) by trapping venous emboli.

Vena Cava filters do not prevent or treat venous thrombosis. In general, the use of vena cava filters is indicated when primary therapy cannot be started, must be stopped, or is insufficient to protect patients from clinically significant PE who are at high risk.

When used in patients at risk of developing Venous Thrombo Embolism (VTE) but who do not yet have it, the purpose of the filter is to prevent clinically significant PE should deep vein thrombosis (DVT) occur.

2. Recommendations

2.1 Filters placed for so-called prophylactic indications do not provide prophylaxis for development of DVT. Only one randomised trial of VC filters in the management of VTE has been published (Decousus, *et al* 1998). The remainder of the evidence comes from un-randomised descriptive case series rather than randomised controlled or even comparative studies of patients receiving anticoagulant therapy or not. These case series are limited by incomplete and short follow up. Therefore recommendations are based on only level IV evidence for the majority of patients requiring a filter.

2.2. Placement of a retrievable (temporary) filter with the intent to discontinue filtration through retrieval or conversion should follow the same indications used for permanent vena cava filters. The decision to use a retrievable filter rather than a permanent filter should be based on the anticipated required duration of protection against clinically significant PE and/or risk of pharmacologic therapy. There are no new unique indications for retrievable vena cava filters distinct from permanent filters.

This is based on the British Committee for Standards in Haematology document "Guidelines on use of Vena Cava Filters".

3. Indications

3.1. Advice regarding the requirement for IVC filter placement may be obtained from any of the Consultant Haematologists with an interest in VTE (Dr Styliani Salta, Dr Sandhya Munireddy, Dr Amy Webster). It is envisaged if the indication for filter placement falls outside these guidelines then the patient should be discussed.

3.2. IVC filters are indicated to prevent PE in patients with VTE who have a contraindication to anticoagulation (grade B level III)

3.3 IVC filter insertion may be considered in selected patients with PE despite therapeutic anticoagulation. Alternative treatment options such as long-term high-intensity oral anti anticoagulation therapy (NE target 3.5) or low molecular weight heparin should be considered prior to VC filter placement, particularly in patients with thrombophilic disorders (e.g. antiphospholipid syndrome) or cancer (grade C, level IV). VC filters should be avoided in patients with cancer as the risk of filter related thrombotic complications appears higher in these patients (Hann &Strieff 2005)

3.4. IVC filters might be appropriate in any preoperative patient with recent VTE (within 1 month) in who anticoagulation must be interrupted. An IVC filter is recommended in patients with thrombus extending above the inguinal ligament who are having abdominal/pelvic surgery and in patients undergoing surgery to the affected leg within one week of VTE and should be considered in such patients for up to one month after VTE. Retrievable VC filters should be considered where a temporary contraindication to anticoagulation exists (grade C, level IV)

3.5. IVC filter insertion may be considered in pregnant patients who have contraindications to anticoagulation or develop extensive VTE shortly before delivery (within 2 weeks). If required retrievable filters are indicated in this situation (grade c, level IV)

3.6. Anticoagulation should be considered in patients with a VC filter when a temporary contraindication to anticoagulant therapy is no longer present. Insufficient data exists to support a recommendation that all filter recipients should be treated with indefinite anticoagulation regardless of their risk of recurrent thrombosis (grade c, level IV). The decision as to whether or not to introduce anticoagulant therapy should be based on the perceived underlying thrombotic risk of the condition and the likelihood of anticoagulant therapy related bleeding.

3.7. IVC filters are not indicated in unselected patients with VTE who will receive conventional anticoagulation therapy (grade A, level Ib)

3.8. Free-floating thrombosis in not an indication for insertion if an IVC filter (grade B, level III)

3.9. Thrombolysis is not an indication for a filter insertion. If a filter is placed it should be a retrievable filter (grade C, level IV)

3.10. No particular filter appears superior to others. Removable filters should be used, if available, for patients with short-term contraindication to anticoagulation therapy (e.g. approximately 2 weeks) (grade C, level IV)

3.11. Patients should have continued medical follow up. If there are any new symptoms then imaging or filter is recommended.

3.13 IVC filter removal recommendation will depend on the manufacturer. Filters that have been in situ greater than the recommended time can still be removed but the patient should be consented appropriately.

3.14 Vena Cava Filters should be considered in any patient with chronic thromboembolic pulmonary hypertension (CTEPH) undergoing pulmonary endarterectomy (grade C, level IV).

4. Audit and Monitoring Indicators

4.1. Clinically apparent recurrent PE should occur in less than 2.7% of patients in the first six months following permanent IVC filter placement.

4.2. Complication rates should be within acceptable limits.

Immediate complications:

- Misplacement (1.3%)
- Pneumothorax (0.02%)
- Haematoma (0.6%)
- Air embolism (0.2%)
- Carotid artery punctures (0.04%)
- Arteriovenous fistula (0.02%)

Early complications:

- Insertion site thrombosis (8.5%)
- Infection

Late complications:

- Recurrent DVT (21%)
- VC thrombosis (2 to 10%)
- Post-thrombotic syndrome (15-40%)
- Venous penetration (0.3%)
- Filter migration (0.3%)
- Filter tilting and fracture
  Entrapment of guide wires

5. Consent

5.1 The following should be noted on the consent form as risks:
Groin haematoma
Increased risk of symptomatic leg or IVC thrombosis and post thrombotic syndrome

There is a patient leaflet titled “Information for patients having a vena cava filter”, DMS document (13864)

6. Further information / References

6.1. Filters may be used when there is a contraindication to anticoagulation. A non-randomised retrospective case series did not identify a difference in outcome between patients treated with filters and those treated with anticoagulation (Jones and Fink 1994). From an overview of case-series and a population-based observational study VC filters appear to be less effective than anticoagulation for preventing PE in patients with VTE (Hann and Streiff 2005, Streiff 2000). The risk of PE after IVC filter placement without anticoagulation is about 3%, mean follow up 15 months (range 0-81 months) (Hann and Streiff 2005, Streiff 2000).

6.2. Vena cava filters are sometimes used in patients who suffer PE despite anticoagulation. In such patients it is important to ensure that apparent anticoagulant failure was not due to a sub therapeutic intensity of anticoagulation. Furthermore, consideration should be given to increasing the target International Normalised Ratio (INR), for example to 3.5, in patients on oral anticoagulant therapy who develop recurrent VTE with a target of 2.5 and an INR greater than 2.0 at the time of recurrent thrombosis (Baglin*, et al* 2006, British Committee for Standards in Haematology 1998). Patients with cancer have a higher incidence of oral anticoagulant failure and should be considered for long-term therapeutic dose LMWH (Baglin*, et al* 2006). VC filters should be avoided in patients with cancer as the risk o f filter-related thrombotic complications appears higher in patients with cancer, without any
Evidence of survival benefits (Hann and Streiff 2005).

6.3. The risk of Thromboembolism declines as time passes after an episode of VTE. During the first 3 months post-thrombosis the risk of recurrence in the absence of anticoagulation is about 50%, 40% during the first month and 10% during the subsequent two months. (Kearon and Hirsh 1997). Therefore, a VC filter should be considered in any patient who requires discontinuation of anticoagulation or cannot receive anticoagulation as a result of an operative procedure that must be performed within 1 month of their thrombotic event.

6.4. VTE causes morbidity and mortality during pregnancy. While the vast majority of pregnant patients with VTE can be managed with conventional anticoagulation occasional patients develop extensive VTE shortly before delivery (within 2 weeks). In these patients, or patients with contraindications to anticoagulation at high risk of Thromboembolism, placement of a VC filter should be considered. Use of vena cava filters for VTE during pregnancy is limited to case reports and small case series. (Aburahma and Mullins 2001, Cheung*, et al* 2005, Hux*, et al* 1986). Clinical follow up of limited intensity and/or duration has not identified any filter-related complications so far. Nevertheless, retrievable filters would appear to be a particularly attractive option for such patients, given the young age of potential recipients and limited follow up data available for this patient population.

6.5. the most frequent complication of VC filters is recurrent venous thrombosis. Also PE may occur. Therefore, it is common practice to initiate anticoagulation after filter insertion if and when there is no longer a contraindication to anticoagulant therapy (Streiff 2000). However, case-series have not demonstrated a benefit from introducing anticoagulation for the sole purpose of preventing filter related thrombotic events (Jones and Fink 1994, Ortega*, et al* 1998). This result may have been because of an inadequate intensity of anticoagulation. In the long-term follow up of patients in the PREPIC study, 43% of patients who develop recurrent Thromboembolism were on anticoagulation. The imperfect protection afforded by anticoagulation and the significant cumulative incidence of major (14.3%) and fatal bleeding (4.3%) during the study period suggest that anticoagulant therapy for patients with VC filters should be guided by an assessment of the patient's risk of recurrent VTE and major bleeding, and not the presence of the filter alone (The PREPIC Study Group 2005).

6.6. In the randomised study by Decousus *et al* 400 patients with proximal DVT (Deep Vein Thrombosis) who were considered to be at high risk of PE were randomised to

filter placement or not (Decousus*, et al* 1998). Patients had ventilation-perfusion lung (V/Q) scans at baseline and between days 8 to 12. All patients were also treated with anticoagulant therapy:

• At day 12 there were fewer new PEs demonstrated by V/Q in the filter group but there was no significant difference in symptomatic PE (filter 1.1% versus no filter 2.6%, odds ratio 0.40, 95% CI 0.08 to 2.1, p=0.25).

• At 2 years recurrent DVT was significantly more frequent in the filter group (20.8% versus 11.8%, odds ratio 1.87, 95% CI 1.10 to 3.20, p = 0.02). Symptomatic PE was not significantly less in the filter group (3.4% versus 6.3%, odds ratio 0.50, 95% CI 0.19 to 1.33, p = 0.16) and mortality and bleeding were not different.

• After 8 years of follow up, the filter group had suffered fewer PE (6.2% versus 15.1%, p=0.01) but had a high incidence of DVT (36.7% versus 27.5%, p=0.042). No difference in mortality was noted (48.1% versus 51.0%). Less than fifty percent of patients were on anticoagulation more than one year and only thirty-five percent of patients in both groups received vitamin K antagonists over the entire 8-year period. These results indicate that VC filters provide greater protection against PE than a limited course of anticoagulation but are associated with a greater risk of DVT and provide no mortality benefit (The PREPIC Study Group 2005). In contrast, a large California population-based observational study of 4044 patients with a filter and 70,687 patients without a filter(controls presumably treated with anticoagulation) conducted by White et al. found that patients with filters were just as likely to suffer new PE as patients without filters (White*, et al* 2000). The risk of DVT was increased two-fold in filter recipients. Therefore in patients who will also receive anticoagulant therapy, the use of a VC filter appears to reduce the incidence of PE but increases the incidence of DVT and has no significant impact upon overall mortality.

6.7. Several studies, including a large randomised study (Decousus*, et al* 1998, The PREPIC Study Group 2005) have failed to show that filters reduce mortality due to PE in anticoagulated patients. In a prospective study of 95 patients the incidence of PE was not greater in patients with free-floating thrombus (n = 62) compared to those without (n = 28), 3.3% versus 3.7% (level III). Therefore, insufficient data exist to support routine filter insertion in patients with free-floating thrombus (Pacouret*, et al* 1997).

6.8. There are case-reports of patients with DVT treated with systemic Thormbolysis and who subsequently developed fatal PE. However, these patients were high-risk patients selected specifically for thrombolytic therapy. Registry data indicate that catheter-directed thrombolysis may be associated with a lower risk of PE than systemic thrombolysis but this is not proven (Hann and Streiff 2005, Mewissen*, et al* 1999). VC filters have not been shown to reduce the incidence of fatal PE during thrombolysis. If a VC filter is used a retrievable filter should be considered.

6.9. The range of filters available has been reviewed recently and most filters appear to be equivalent (Hann and Streiff 2005). In view of the long-term complications of filters the development and validation of effective and safe removable filters would be of benefit to patients with a short-term contraindication to anticoagulant therapy. Two general types of removable filter are available: tethered filtration devices and retrievable filters. Clinical studies are required to determine the relative safety and efficacy of these devices. The advantage of retrievable filters is that they can be either left in situ during the high risk phase of developing a PE and subsequently removed or

can be left in situ permanently in patients in whom the clinical indication changes towards permanent cava interruption. Tethered filters are associated with percutaneous infection risk along the tether. Most manufacturers recommend that retrievable filters should be removed within 10 to 14 days
of implantation although some have been successfully removed over a month after placement (Hann and Streiff 2005). The choice of filter will often depend on local availability and interventional radiological expertise.

7. References

British Committee for Standards in Haematology document " Guidelines on use of Vena Cava Filters".

Others:

1. Aburahma, A.F. & Mullins, D.A. (2001) Endovascular caval interruption in pregnant patients with deep vein thrombosis of the lower extremity. *Journal of Vascular Surgery,* **33,** 375-378.

2. Baglin, T.P., Keeling, D.M. & Watson, H.G. (2006) Guidelines on oral anticoagulation (warfarin): third edition--2005 update. *British Journal of Haematology,* **132,** 277-285.

3. British Committee for Standards in Haematology (1998) Guidelines on oral anticoagulation: third edition. *British Journal of Haematology,* **101,** 374-387.

4. Cheung, M.C., Asch, M.R., Gandhi, S. & Kingdom, J.C. (2005) Temporary inferior vena caval filter use in pregnancy. *Journal of Thrombosis and Haemostasis,* **3,** 1096-1097.

5. Crochet, D.P., Brunel, P., Trogrlic, S., Grossetete, R., Auget, J.L. & Dary, C. (1999) Long-termfollow-up of Vena Tech-LGM filter: predictors and frequency of caval occlusion. *Journal of Vascular Interventional Radiology,* **10,** 137-142.

6. Decousus, H., Leizorowich, A., Parent, F., Page, Y., Tardy, B., Girard, P., Laporte, S., Faivre, R., Charbonier, B., Barral, F.-G., Huet, Y., Simonneau, G. & Group, f.t.P.d.R.d.E.P.p.I.C.S. (1998) A clinical trial of vena caval filters in the prevention of pulmonary embolism in patients with proximal deep-vein thrombosis. *New England Journal of Medicine,* **338,** 409-415.

7. Hann, C.L. & Streiff, M.B. (2005) the role of vena caval filters in the management of venous thromboembolism. *Blood Reviews,* **19,** 179-202.

8. Hux, C.H., Wapner, R.J., Chayen, B., Rattan, P., Jarrell, B. & Greenfield, L. (1986) Use of the Greenfield filter for thromboembolic disease in pregnancy. *American Journal of Obstetrics and Gynecology,* **155,** 734-737.

9. Jones, B.T. & Fink, J.A. (1994) A prospective comparison of the status of the deep venous systemafter treatment with intracaval interruption versus anticoagulation. *Journal of the American College of Surgeons,* **178,** 220-222.

10. Kearon, C. & Hirsh, J. (1997) Management of anticoagulation before and after elective surgery. *New England Journal of Medicine,* **336,** 1506-1511.

11. Mewissen, M.W., Seabrook, G.R., Meissner, M.H., Cynamon, J., Labropoulos, N. & Haughton, S.H. (1999) Catheter-directed thrombolysis for lower extremity deep venous thrombosis: report of a national multicenter registry. *Radiology,* **211,** 39-49.

12. Ortega, M., Gahtan, V., Roberts, A., Matsumoto, T. & Kerstein, M. (1998) Efficacy of anticoagulation post-inferior vena caval filter placement. *American Surgeon,* **64,** 419-423.

13. Pacouret, G., Alison, D., Pottier, J.M., Bertrand, P. & Charbonnier, B. (1997) Free-floating thrombus and embolic risk in patients with angiographically confirmed proximal deep venous thrombosis. A prospective study. *Archives of Internal Medicine,* **157,** 305-308.

14. Streiff, M.B. (2000) Vena caval filters: a comprehensive review. *Blood,* **95,** 3669-3677.

15. The PREPIC Study Group (2005) Eight-year follow-up of patients with permanent vena cava filters in the prevention of pulmonary embolism: the PREPIC (Prevention du Risque d'Embolie Pulmonaire par Interruption Cave) randomized study. *Circulation,* **112,** 416-422.

16. White, R.H., Zhou, H., Kim, J. & Romano, P.S. (2000) A population-based study of the effectiveness of inferior vena cava filter use among patients with venous thromboembolism. *Archives of Internal Medicine,* **160,** 2033-2041.

8. Legal Liability Guideline Statement

(This statement has been developed by Corporate and legal affairs. It must be included in all clinical guidelines and the wording must not be altered in any way)

Guidelines issued and approved by the Trust are considered to represent best practice. Staff may only exceptionally depart from any relevant Trust guidelines providing always that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible healthcare professional' it is fully appropriate and justifiable - such decision to be fully recorded in the patient's notes