bjh guidelines

Guidelines on use of vena cava filters

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The guideline group was selected to be representative and responsive to the UK practice. MEDLINE and the COCHRA-NE database were searched systematically for publications in English from 1998. Only one randomised review of vena cava (VC) filters was identified (Decousus et al, 1998) and the guideline reflects the findings of that review and an updated review published in 2005 (Hann & Streiff, 2005). The writing group produced the draft guideline, which was subsequently revised by consensus of the members of the Haemostasis and Thrombosis Task Force for the British Committee for Standards in Haematology. The guideline was reviewed by a multidisciplinary sounding board, the British Committee for Standards in Haematology (BCSH) and the British Society for Haematology (BSH) and comments incorporated where appropriate. Criteria used to quote levels and grades of evidence are as outlined in Appendix 3 of the Procedure for Guidelines Commissioned by the BCSH (http://www. bcshguidelines.com/process1.asp#App3).

The objective of this guideline was to provide healthcare professionals with clear guidance on the management of VC filters. In all cases individual patient circumstances may dictate an alternative approach.

Summary of key recommendations

- VC filters are indicated to prevent pulmonary embolus (PE) in patients with venous thromboembolism (VTE) who have a contraindication to anticoagulation (grade B, level III).
- 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.

- VC filters are not indicated in unselected patients with VTE who will receive conventional anticoagulant therapy (grade A, level Ib).
- VC filter insertion may be considered in selected patients with PE despite therapeutic anticoagulation. Alternative treatment options, such as long-term high-intensity oral anticoagulant therapy [international normalised ratio (INR) target 3.5] or low molecular weight heparin (LMWH), 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 filter insertion may be considered in pregnant patients who have contraindications to anticoagulation or develop extensive VTE shortly before delivery (within 2 weeks). Retrievable filters should be considered (grade C, level IV).
- Free-floating thrombus is not an indication for insertion of a VC filter (grade B, level III).
- Thrombolysis is not an indication for filter insertion. If a filter is used a retrievable filter should be used if available (grade C, level IV).
- VC filters should be considered in any pre-operative patient with recent VTE (within 1 month) in whom anticoagulation must be interrupted. Retrievable VC filters should be considered in this situation where a temporary contraindication to anticoagulation exists (grade C, level IV).
- No particular filter appears superior to others. Removable filters should be used, if available, for patients with a short-term contraindication to anticoagulant therapy (e.g. approximately 2 weeks) (grade C, level IV).

1. Situations in which VC filters might be considered

The only purpose of a VC filter is to prevent PE. Only one randomised trial of VC filters in the management of VTE has been published (Decousus *et al*, 1998). In that study, all

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patients received heparin treatment initially and 99% of patients were discharged on oral anticoagulant therapy. The remainder of the evidence comes from unrandomised descriptive case series rather than randomised controlled or even comparative studies of patients receiving anticoagulant therapy or not. These case series are, in many instances, limited by incomplete and short follow up. Therefore, recommendations are based on only level IV evidence for the majority of patients requiring a VC filter, i.e. patients with a contraindication to anticoagulation.

1.1. Are filters indicated in patients with VTE and a contraindication to anticoagulant therapy?

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 & 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 (Streiff, 2000; Hann & Streiff, 2005). The risk of PE after filter placement without anticoagulation is about 3%, mean follow up 15 months (range 0–81 months) (Streiff, 2000; Hann & Streiff, 2005).

Recommendation

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

1.2. Should anticoagulant treatment be started when there is no longer a contraindication?

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 & 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 (Prevention du Risque d'Embolie Pulmonaire par Interruption Cave) study, 43% of patients who developed 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).

Recommendation

Anticoagulation should be considered 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 therapyrelated bleeding.

1.3. Are filters indicated in patients receiving conventional anticoagulant therapy?

In the randomised study by Decousus *et al* (1998), 400 patients with proximal deep vein thrombosis (DVT) who were considered to be at high risk of PE were randomised to filter placement or not. Patients had ventilation–perfusion lung (V/ Q) scans at baseline and between days 8 and 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% vs. no filter 2·6%, odds ratio 0·40, 95% CI 0·08–2·1, P = 0.25).
- At 2 years, recurrent DVT was significantly more frequent in the filter group (20.8% vs. 11.8%, odds ratio 1.87, 95% CI 1.10–3.20, P = 0.02). Symptomatic PE was not significantly less in the filter group (3.4% vs. 6.3%, odds ratio 0.50, 95% CI 0.19–1.33, 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% vs. 15.1%, P = 0.01) but had a high incidence of DVT (36.7% vs. 27.5%, P = 0.042). No difference in mortality was noted (48.1% vs. 51.0%). Less than 50% of patients were on anticoagulation for more than 1 year and only 35% 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* (2000) found that patients with filters were just as likely to suffer new PE as patients without filters. 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.

Recommendation

Vena cava filters are not indicated in unselected patients with VTE who will receive conventional anticoagulant therapy (grade A, level Ib).

1.4. Are filters indicated in patients with apparent anticoagulant failure?

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 subtherapeutic intensity of anticoagulation. Furthermore, consideration should be given to increasing the target 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 >2.0 at the time of recurrent thrombosis (British Committee for Standards in Haematology, 1998; Baglin et al, 2006). 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 of filter-related thrombotic complications appears higher in these patients, without any evidence of survival benefit (Hann & Streiff, 2005).

Recommendation

Vena cava filter insertion may be considered in selected patients with PE despite therapeutic anticoagulation. Alternative treatment options, such as long-term high-intensity vitamin K antagonist therapy (INR target 3.5) or LMWH therapy, should be generally considered prior to VC filter placement, particularly in patients with thrombophilic disorders (e.g. antiphospholipid syndrome) or cancer (grade C, level IV).

1.5. Are VC filters indicated for treatment of VTE during pregnancy?

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 and other patients with acute VTE and contraindications to anticoagulation, placement of a VC filter will occasionally be considered. Use of VC filters for VTE during pregnancy is limited to case reports and small case series (Hux *et al*, 1986; Aburahma & Mullins, 2001; Cheung *et al*, 2005). Therefore, the use of filters for primary prophylaxis, i.e. in the absence of DVT, is not recommended. For patients with DVT but with contraindications to anticoagulation, the relative risks and benefits of anticoagulation *versus* filter must be carefully considered. 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 when a filter is used, given the young age of potential recipients and limited follow-up data available for this patient population.

Recommendation

VC filter insertion may be considered in pregnant patients who have contraindications to anticoagulation and develop extensive VTE shortly before delivery (within 2 weeks). Retrievable filters should be considered (grade C, level IV).

1.6. Are filters indicated in patients with free-floating thrombus?

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% vs. 3·7% (level III). Therefore, insufficient data exist to support routine filter insertion in patients with free-floating thrombus (Pacouret *et al*, 1997).

Recommendation

Free floating thrombus is not an indication for insertion of a VC filter (grade B, level III).

1.7. Are filters indicated in patients receiving thrombolytic therapy for DVT?

There are case reports of patients with DVT treated with systemic thrombolysis 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 (Mewissen *et al*, 1999; Hann & Streiff, 2005). VC filters have not been shown to reduce the incidence of fatal PE during thrombolysis. If a VC filter is used, a retrievable one should be considered.

Recommendation

Thrombolysis is not an indication for filter insertion. A retrievable filter should be used if available (grade C, level IV).

1.8. Are filters indicated in preoperative patients for DVT?

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 2 months. (Kearon & 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. Retrievable VC filters should be considered. Although VC filters have been used for VTE prophylaxis in high-risk patient populations, evidence supporting their value is lacking and so careful consideration of benefit and risk is required in each case (Hull, 2005).

Recommendation

Vena cava filters should be considered in any preoperative patient with recent VTE (within 1 month) in whom anticoagulation must be interrupted. Retrievable VC filters should be considered where a temporary contraindication to anticoagulation exists (grade C, level IV).

1.9. Are filters indicated for patients with chronic postembolic pulmonary hypertension undergoing pulmonary endarterectomy?

Almost 4% of patients develop symptomatic chronic thromboembolic pulmonary hypertension (CTEPH) at 2 years after an episode of PE (Pengo *et al*, 2004). Pulmonary endarterectomy has been demonstrated to be the most effective treatment for patients with CTEPH (Jamieson *et al*, 2003). Although no randomised controlled trials have been performed, VC filters are commonly placed preoperatively in these patients and one small case series identified inadequate caval filtration as a common abnormality in patients requiring re-operative pulmonary endarterectomy (Mo *et al*, 1999). Therefore, placement of a VC filter should be considered in preoperative patients undergoing pulmonary endarterectomy. Given the absence of data substantiating the value of VC filters, their use in the broader population of patients with CTEPH should be considered on a case-by-case basis.

Recommendation

Vena cava filters should be considered in any patient with CTEPH undergoing pulmonary endarterectomy. Placement of a VC filter may also be beneficial for other patients with CTEPH (grade C, level IV).

2. Which filter should be used

The range of filters available has been reviewed recently and most filters appear to be equivalent (Hann & 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 10–14 d of implantation although some have been successfully removed over a month after placement (Hann & Streiff, 2005). The choice of filter will often depend on local availability and interventional radiological expertise.

Recommendation

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

3. Filter location

Inferior VC (IVC) filters are typically placed beneath the renal veins. Suprarenal placement may be required when thrombus extends up to the renal veins. A potential complication of suprarenal placement is renal vein occlusion and impaired renal function. Exceptionally, filters can be placed in the superior VC (SVC) but given the paucity of clinical data, SVC filters should be restricted to patients with an absolute contraindication to anticoagulation and removable filters should be considered, when available.

A study has examined if the additional use of selective venography, compared with nonselective venography alone, reveals more abnormal anatomical findings that lead to changes in VC filter position. Twenty-three per cent of patients had either an abnormal finding or aberrant anatomy, and most of these patients required a major change in VC filter position. This led the authors to conclude that visualisation of the VC for filter deployment should be performed in most patients (Danetz *et al*, 2003).

4. Complications of filter placement

Immediate, early and late complications have been reviewed (Streiff, 2000; Hann & Streiff, 2005). Fatal complications are <0.5%. Complication rates are taken from the review by Hann & Streiff, 2005).

4.2 Immediate complications

- Misplacement (1.3%)
- Peumothorax (0.02%)

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- Haematoma (0.6%)
- Air embolism (0.2%)
- Carotid artery puncture (0.04%)
- Arteriovenous fistula (0.02%)

These complications, related to vascular access, can be largely avoided by use of ultrasound and fluoroscopy to guide the initial venepuncture and subsequent filter placement. In patients who have received anticoagulant treatment and require urgent filter insertion interventional radiologists tend to accept an INR or activated partial thromboplastin time ratio of 1.5 as being the upper limit for filter insertion.

4.2. Early complications

- Insertion site thrombosis (8.5%)
- Infection

4.3. Late complications

- Recurrent DVT (21%)
- IVC thrombosis (2–10%)
- Post-thrombotic syndrome (15–40%)
- IVC penetration (0.3%)
- Filter migration (0.3%)
- Filter tilting and fracture
- Entrapment of guidewires

Inferior VC occlusion due to thrombosis increases over time. A radiological surveillance study identified IVC occlusion rates of 22% at 5 years and 33% at 9 years of follow up (Crochet *et al*, 1999). Anticoagulation did not appear to influence the rate of occlusion. Fifty per cent of patients with occlusion had leg swelling.

A more recently recognised long-term complication of VC filters is the entrapment of guidewires that are used during central venous catheter placement or interventional vascular procedures. In some instances, vigorous attempts to remove entrapped guidewires have resulted in vascular damage and displacement of VC filters. This complication can be best avoided by clearly indicating in the clinical records that a filter has been inserted and the patient wearing a warning bracelet. Straight-tipped guidewires should be used when this is a potential problem as they are less likely to become entrapped. If a guide wire is entrapped an interventional radiologist or vascular surgeon should be consulted. This complication can be avoided by the use of fluoroscopy during the interventional procedure and use of non-curved catheters and hydrophilic (floppy) wires.

Theoretically, filter migration could result from magnetic resonance (MR) imaging but this has not yet been reported as a problem. Nevertheless, an MR procedure should not be performed if there is any possibility that the filter is not positioned properly or is not firmly in place. Stainless steel filters produce artefacts on MR imaging.

5. What is the appropriate follow up for patients with permanent VC filters?

As VC filters are associated with an increased incidence of DVT and IVC thrombosis, the Vena Cava Filter Consensus Conference recommended that all patients with VC filters receive routine clinical and, preferably, objective radiological follow-up evaluations (Participants in the Vena Caval Filter Consensus Conference., 1999). Clinical evaluation should include an assessment of subsequent episodes of VTE, physical findings of post-thrombotic syndrome and current use of anticoagulation as well as any complications resulting in the discontinuation of anticoagulation. Recommended objective radiological testing included the use of abdominal radiographs to determine placement stability, duplex examination of the lower extremities to identify recurrent DVT or chronic venous insufficiency and scanning to identify extracaval filter extension and caval thrombosis.

Recommendation

Patients with permanent VC filters should receive routine follow up for complications associated with VC filters or VTE (grade C, level IV).

Disclaimer

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