CASE BASED REVIEWS

Gone in 60 days: our first experience with a bioconvertible IVC filter

Gerard Lambe[1] · Johnny O' Mahony[1] · Michael Courtney[1] · Noel Donlon[2] · Claire Donohoe[2] · JMark Ryan[1]

Abstract

The Sentry bioconvertible IVC filter (Boston Scientific, MA, USA) contains a bioabsorbable filament which hydrolyses after 60 days, allowing the arms of the filter to spring open, retract into the vessel wall and endothelialise, leaving an unobstructed IVC lumen.

It is a novel treatment option for patients at transient risk of pulmonary emboli with a contraindication to anticoagulation. The device provides similar protection to other currently available devices against pulmonary emboli with minimal complications. It represents an effective alternative to retrievable filters, the removal of which is variously not attempted, not possible or associated with high complication rates.

We review the literature which underpins the development of the bioconvertible filter. We describe our first deployment of the filter in an 85-year-old female with gastric malignancy (who subsequently underwent a subtotal gastrectomy) with a history of anaemia and previous pulmonary emboli. The availability of a bioconvertible filter constitutes a further step forward in the management of patients with potential or active thromboembolic disease.

Keywords Anticoagulation · Bioconversion · Deep venous thrombosis · IVC filter · Pulmonary embolism · Retrieval

Background

The Sentry bioconvertible inferior vena cava (IVC) filter is designed to provide temporary protection against pulmonary embolic disease during transient periods of high risk [1]. The filter is made from a single piece of laser-cut nitinol formed into a cylindrical frame. The filter is designed to bioconvert after 60 days when a bioabsorbable filament made of poly-p-dioxanone hydrolyses and releases the arms of the filter. The arms retract into the vessel wall and are endothelialised, leaving an unobstructed IVC lumen (Fig. 1).

The rationale for its use and development is multifactorial.

a) The highest risk period for pulmonary emboli is the first 60 days after an index event such as hospitalisation, trauma or surgery. The majority of pulmonary emboli occur within the first 30 days [2, 3].

b) There are several complications associated with unretrieved filters including recurrent deep vein thrombosis (DVT), IVC thrombosis, organ penetration, strut fracture and migration. The risks increase with the length of time the filter is in situ [4].

c) Retrievable filters are often never retrieved for a variety of reasons, even when the initial indication for pulmonary embolic prophylaxis has passed. Retrieval rates are rarely greater than 50% and sometimes as low as 8.5% [5–7]. When retrieval is attempted, it is often technically challenging, success rates are variable and the procedure is associated with high complication rates [8].

d) Retrieval of IVC filters involves significant time and expense. Medicare data in the USA suggests that the payment provided for filter removal does not compensate for the expense of the procedure [9].

The Sentry filter has been evaluated in a multicentre prospective trial of 129 patients with either documented DVT/PE or at temporary risk of DVT/PE. It has shown a high rate of successful bioconversion, strong protection against pulmonary emboli and a low rate of device-related complications through 2 years of follow-up [10].

✉ Gerard Lambe
gerard.lambe@ucdconnect.ie

1   Radiology Department, St. James's Hospital, James's Street, Dublin 8, Ireland

2   Department of Upper GI Surgery, St. James's Hospital, James's Street, Dublin 8, Ireland
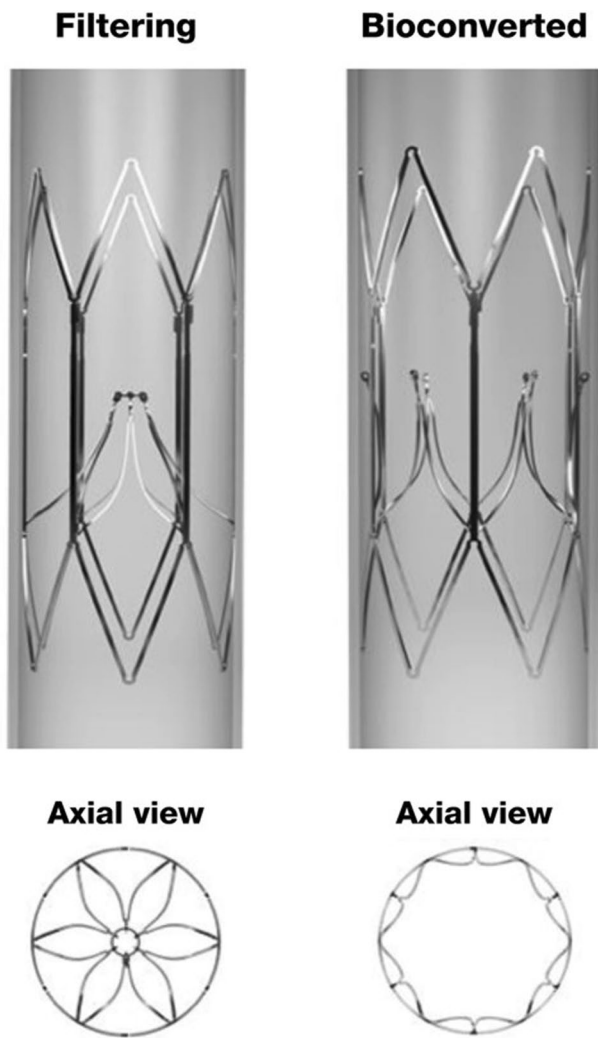
Filtering

Bioconverted

Axial view

Axial view

Fig. 1 Photographs from Dake et al. [25] of the Sentry IVC filter in the filtering configuration (left) and in the bioconverted configuration (right). The filter contains a bioabsorbable filament which is designed to hydrolyse after 60 days, allowing the arms of the filter to spring open, retract into the vessel wall and endothelialise, leaving an unobstructed IVC lumen

We present what we believe to be the first use of a bioconvertible IVC filter in the Republic of Ireland.

Case report

An 85-year-old female was admitted electively under the Upper GI Surgery team for a staging laparoscopy for gastric malignancy. Our institution is a tertiary referral university teaching hospital and the National Centre for Oesophageal and Gastric Cancer.

She had a recent diagnosis of COVID-19 pneumonia in another hospital which was complicated by subsegmental pulmonary emboli. She was on treatment with subcutaneous Tinzaparin injections. She had experienced prior pulmonary emboli 8 years earlier which had been managed with Warfarin and subsequently a novel oral anticoagulant (NOAC).

Her past medical history was significant for ischaemic heart disease (with an ejection fraction of less than 30%), type 2 diabetes mellitus, hypertension and hyperlipidaemia. Her past surgical history consisted of a hysterectomy and open appendicectomy.

She was an ex-smoker who lived with her son and daughter-in-law. She was independently mobile with a frame at baseline. However, she was found to be breathless on minimal exertion on clinical evaluation.

A full blood count revealed a haemoglobin of 9.9 g/dL. Her anaemia was felt to be secondary to her gastric tumour, and a decision was made to hold her anticoagulation until a subtotal gastrectomy had been performed.

The patient's case was discussed with Interventional Radiology. It was decided, given the patient would remain at risk of further pulmonary emboli for a transient period until

Fig. 2 A guidewire is advanced into the IVC

her gastrectomy and for a short period after her gastrectomy, that she would be a suitable candidate for a bioconvertible IVC filter.

The procedure was discussed with the patient in Interventional Radiology, and informed consent was provided. The access site in the right groin was cleaned and draped with the patient in a supine position. The right common femoral vein was accessed using a micropuncture set consisting of a 21-gauge needle, a 0.018-inch wire and a 5 French dilator/sheath. A guidewire was advanced into the IVC (Fig. 2).

A venogram was performed by injecting contrast through a catheter to assess for IVC patency, size and anomalies and to identify the location of the renal veins (Fig. 3). The filter

was deployed through a dedicated delivery sheath (Fig. 4). A repeat venogram was performed which confirmed the satisfactory deployment of the filter (Fig. 5). The delivery sheath

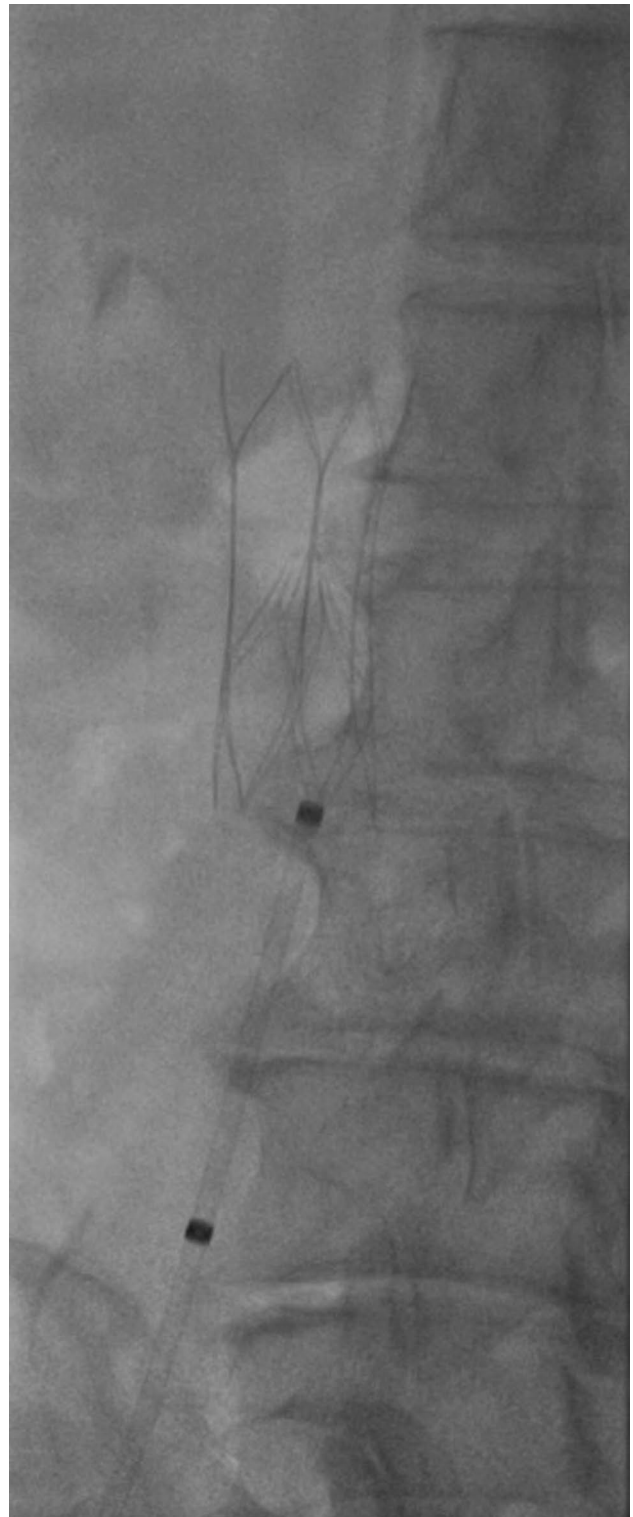**Fig. 3** A venogram is performed which confirms a single, patent IVC and the position of the renal veins
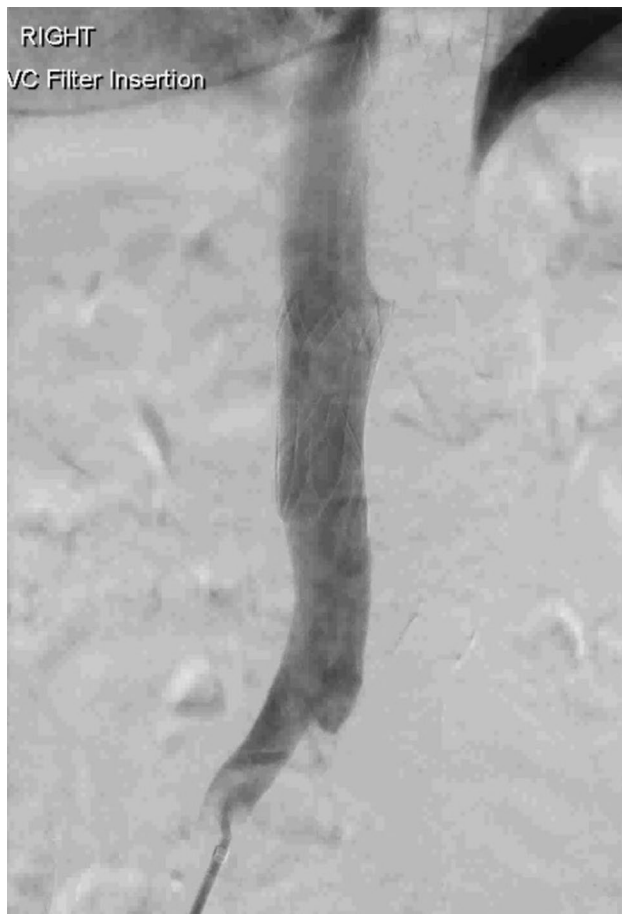

Fig. 4 The filer is deployed in the IVC

Fig. 5 A repeat venogram is performed which confirms satisfactory deployment of the filter

was removed, and haemostasis was achieved with manual compression.

The patient was successfully discharged home the following day. She returned for a subtotal gastrectomy as planned 3 weeks later.
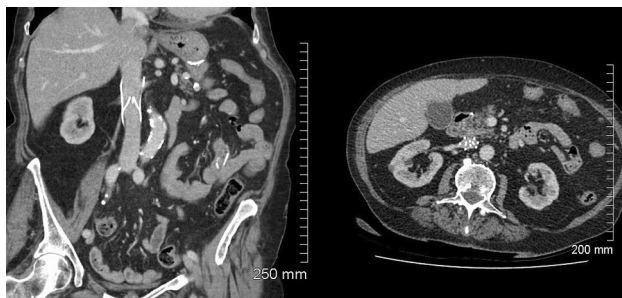

Fig. 6 Coronal (left) and axial (right) CT images in the early post-operative period demonstrate the filter in its expected filtering configuration with the arms of the filter held together by a bioabsorbable filament
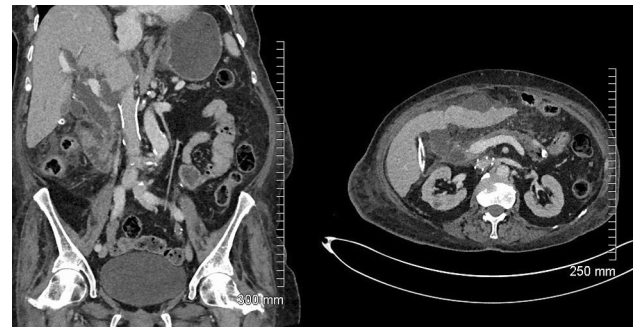

Fig. 7 Coronal (left) and axial (right) CT images between 5 and 6 months later reveal interval bioconversion of the filter. The filter arms have been released and have retracted to the vessel wall leaving an unobstructed lumen

Follow-up CT images demonstrated the filter in its filtering configuration (Fig. 6) and subsequently in its bioconverted configuration (Fig. 7).

Discussion

Venous thromboembolism comprises DVT and PE and represents a major cause of global morbidity and mortality, affecting millions of people every year [11]. It is the third most common cause of death from cardiovascular disease after myocardial infarction and stroke [12, 13].

Anticoagulation is the standard of care for patients with known DVT/PE or at risk of DVT/PE [14]. When anticoagulation is contra-indicated or not effective, an IVC filter may be considered in line with careful patient selection criteria devised by many societies and expert panels [15, 16]. Evidence from systematic reviews has shown that IVC filters are effective at providing mechanical protection against pulmonary emboli [5, 17, 18].

The concept of IVC interruption to prevent the migration of emboli was first mentioned by Armand Trosseau in 1865 [19]. Surgically inserted IVC filters were pioneered in the 1960s but found little favour until a percutaneous insertion technique was introduced by Greenfield in 1973 [20]. This was followed by the emergence of retrievable IVC filters in the 1990s [21]. For the first time, devices could now be removed when the period of high risk for the pulmonary embolic disease had passed.

The retrievable filters were granted approval by the US Food and Drug Administration (FDA) for both temporary and permanent indications, but it was expected that the majority of these filters would be removed. However, this has not been the experience either internationally or in

Ireland. Retrieval rates are as rarely greater than 50% and sometimes as low as 8.5% [5–7]. An Irish study of fifty-seven patients who underwent IVC filter insertion over a 22-month period found that filter retrieval was attempted in 48.9% with a technical removal success rate of 86.9% [22].

Complications associated with long-term filters include DVT, IVC thrombosis, organ penetration, strut fracture and migration. The risks appear to increase with the length of time the filter is in situ [4].

The Sentry device is the world's first bioconvertible IVC filter. It offers protection against pulmonary emboli during a transient risk period without the need for a second procedure to remove it and without the complications of long-term or permanent filters.

The filter was evaluated in a multicentre prospective trial of 129 patients with either documented DVT/PE or at temporary risk of DVT/PE [10]. The rate of new symptomatic PE was 0% ($n = 126$) through one year and 2.4% ($n = 85$) through the second year. Results through the first year compare favourably with PE rates in recent trials of retrievable filters [23, 24]. Both non-fatal PEs in the second year occurred long after the transient risk period and were judged by the Central Events Committee to be unrelated to the device or procedure.

Symptomatic IVC thrombosis occurred in two patients (1.6%) within the first month. Both cases were successfully treated without recurrence. There were no episodes of filter tilting, migration, embolisation, fracture or IVC perforation through 2 years. There were no filter-related deaths. The filter successfully bioconverted in 95.7% of patients at 6 months, 96.4% at 12 months and 96.5% at 24 months.

For patients at transient risk of pulmonary emboli who have a contraindication to anticoagulation, a bioconvertible IVC filter appears to provide strong protection against PEs with minimal complications. It offers a new and effective alternative to retrievable IVC filters which are often not removed and where removal is associated with high complication rates. The availability of a bioconvertible filter in the Republic of Ireland represents another important management tool in the treatment of patients with potential or active thromboembolic disease.

Declarations

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