

The British Society of Interventional Radiology



First UK **Inferior Vena Cava Filter** **Registry Report** **2011**

Prepared by

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Nicholas Chalmers FRCR

on behalf of the British Society of Interventional Radiology

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Dendrite Clinical Systems

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British Society of
Interventional
Radiology

The British Society of Interventional Radiology operates the Inferior Vena Cava filter registry in partnership with Dendrite Clinical Systems Limited. The Society also gratefully acknowledges the assistance of Dendrite Clinical Systems for:

- building, maintaining & hosting the web registry
- data analysis and
- publishing this report.

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Preface

The members of the BSIR can rightly be proud of their achievement in producing another high quality registry report. Our registries demonstrate the continuing commitment of the BSIR and its members in constantly striving to improve standards in the practice of interventional radiology. The IVC filter registry follows on from a series of successful registries such as BIAS (BSIR Iliac Angioplasty & Stenting), ROST (Registry of Oesophageal Stenting), and BDSR (Biliary Drainage & Stenting Registry).

The information in these registries helps us to fulfil key objectives of the Society in terms of improving our understanding of contemporary practice. This helps the BSIR to lead in establishing standards for practice for Interventional Radiology allowing us:

- to look at how we might improve the way we treat our patients both individually and collectively.
- to demonstrate that our individual or collective performance as a unit is in keeping with our peers nationally.

Understanding current practice is only the beginning of this journey and we anticipate that you will use the registry data locally as the basis for audit, and that agencies such as the Royal College of Radiologists, Medicines and Healthcare Products Regulatory Agency and NHS Improvement will be interested to learn from our collective experience.

In this instance we have collected data on 1,255 patients treated with IVC filters with a range of indications and across a wide range of centres. This is a great achievement and both those who contributed data and those who set up, run and analyse the data are to be congratulated for their tenacity. However, we must recognise that the information gathered from registry data does not tell the whole story as we do not capture the data from all operators nor every procedure. We can expect to hear more of this in future possibly linked to best practice tariffs!

The IVC filter registry reviews the indications for placement of IVC filters, compares these with existing guidance and whether temporary retrievable filters are actually being removed as intended. The information presented in this report will be invaluable in helping to guide practice in an important area of interventional radiology, with specific recommendations within the report to make filter placement and retrieval easier.

David Kessel
President, BSIR

Iain Robertson
Vice President, BSIR



Foreword

The contributors to this registry are to be congratulated on collecting such a large body of data on 1,255 patients. It is thanks to the hard work of these contributors that the BSIR is able to produce this valuable report for the benefit of its members and all interventional radiologists.

This report is based on data collected in the BSIR inferior vena cava (IVC) filter registry. One of the key objectives of the BSIR is to help members to objectively assess their own practice in order to improve standards of patient care. This registry aimed to compare United Kingdom practice with CIRSE guidelines, to assess complications rates associated with the different types of IVC filter and to assess the rate of retrieval of filters in those patients where filter placement was intended to be temporary. We sought to achieve at least one year follow-up when possible.

The registry has accumulated a substantial amount of data. Although there are numerous previous case series reported, there are few prospective studies that enable comparison of different types of filter. The registry provides information on how operators are using IVC filters, and suggests some possible differences in complications due to the design of filters which may help guide future practice.

Nicholas Chalmers and Raman Uberoi

on behalf of the British Society of Interventional Radiology



Executive summary

The BSIR Inferior Vena Cava Filter Registry provides an audit of current United Kingdom practice.

This report contains analysis of data on 1,255 caval filter placements and 387 attempted retrievals performed at 68 United Kingdom centres between January 2008 and December 2010. Filter use in the vast majority of patients in the United Kingdom follows accepted guidelines. Filter placement is usually a low-risk procedure, with a major complication rate <0.5%.

Indications for filter placement

The majority of filter placements were undertaken for recognised indications according to CIRSE guidelines (see appendix). The most frequently-recorded indications were :

- pre-operatively for acute deep vein thrombosis (DVT) / pulmonary embolus (PE) 30.3%
- PE with contra-indications to anticoagulation 25.6%
- prophylaxis in high risk patients 21.0%

Few placements did not conform to guidelines, the commonest being DVT associated with malignancy (but without associated PE or surgery).

Filter types

The majority of filters used were of a retrievable type, even when the filter was placed with the intention of leaving it permanently in place. Cook Gunther Tulip and Celect filters constituted the majority, with Bard G2 and Recovery filters, and Cordis Trapease and OptEase accounting for most of the rest.

- Cook Gunther Tulip 39.1%
- Cook Celect 24.3%
- Cordis OptEase 13.7%
- Bard G2 7.6%
- Cordis Trapease 5.5%

Outcomes

Implantation

Over 96% of filters deployed as intended. Of those that did not, tilting was the commonest finding. Deployment was abandoned in one case due to dilated IVC. One filter was retrieved immediately after deployment due to pain. A second required surgical removal due to major penetration of the caval wall during deployment.

Post-deployment

One filter was surgically removed because of pain and a second was surgically removed at laparotomy performed for other reasons: perforation of the caval wall by stent struts was noted.

Filter tilting

Tilting was seen with all of the commonly used filters but was most frequently seen with the Cook Gunther Tulip and Celect filters. Tilting, to the extent of the filter head abutting the caval wall, was a frequent cause of failure to retrieve the filter. Tilting was more likely to occur with a left femoral deployment, than right femoral or jugular.

Filter migration

Few cases of migration of >10 mm were reported. In one case caudal migration was associated with failure to retrieve the filter. There was one case of migration to the intra-hepatic IVC. No instances of cardiac migration were reported.

Filter structural failure

No instances of fracture or significant structural failure were reported.



Filter perforation of the caval wall

Overall perforation rates were low, but, in the absence of systematic CT follow-up, perforation is likely to be under-reported. Perforation was reported most frequently with the Bard G2 and Recovery filters. Perforation was not reported with the Cordis filters.

- Bard G2 13.9%
- Bard Recovery 10.0%
- Cook Gunther Tulip 1.7%
- All others <0.3%

Retrieval

- Of the filters intended for temporary placement, retrieval was attempted in 77.8%. Retrieval was technically successful in 82.3%. The time interval between placement and attempted retrieval differed between the filters, reflecting the advice in the *Instructions for Use*. The OptEase filter had the shortest median dwell time at 12 days.
- The success of retrieval was significantly reduced for implants left in place for >9 weeks *versus* those with shorter dwell time.
- There was no major difference in retrieval success of different filter makes, with Bard filters achieving the highest success rates, despite the longest median dwell time at 77 days.
- Retrieval was associated with few minor complications and no serious complications.

Pulmonary embolism and IVC or lower limb thrombosis during long-term follow-up

- Pulmonary embolism was reported in 16 cases during follow-up and was reported to be the cause of death in 6, but this is not supported by objective evidence in most cases.
- New lower limb deep vein thrombosis and / or IVC thrombosis was reported in 88 cases after filter placement with no significant difference in incidence between filter types.

Conclusions

The contributors to this registry are to be congratulated on producing the largest prospective collection of data on the practice of IVC filters placement in the world, which will help guide future practice in the United Kingdom.

There are several *caveats*, however. Inevitably, not all United Kingdom centres participated and the proportion of cases registered by participating centres is unknown. There is no independent external data monitoring, and there have been some instances of differences in interpretation of certain data items between participants. There was no systematic clinical or imaging follow-up regime, thus data on long-term filter integrity, migration and caval wall perforation is derived from clinically driven investigations. This detracts from the quality of some of the data analysis and limits our confidence in some of the subsequent conclusions

However, this report will provide Interventional Radiologists with an improved understanding of the technical aspects of IVC filter placement to help improve practice, and the potential consequences of caval filter placement so that we are better able to advise patients and referrers.

Recommendations

- When a right femoral access is not available for the placement of an IVC filter a jugular approach should be used when possible.
- Where a filter is placed with the intention of removal, procedures should be put in place to avoid the patient being lost to follow up. This could be done simply by booking an appointment on the Radiology Information System.
- Filter retrieval appears to be the most successful before 9 weeks and patients should be booked for removal within this time-frame.



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Contents

Preface	4
Foreword	5
Executive summary	6
Contributors	8
Background	16
IVC filters	16
The Inferior Vena Cava Filter Registry	17
A note on the conventions used throughout this report	18
Conventions used in tables	18
Conventions used in graphs	19
Pre-procedure data	
Data acquisition	22
Contributing hospitals	23
Patient demographics	24
Age and gender	24
Indication	26
Indication for placement	26
Prophylaxis in high risk patients	28
Placement intention	29
The procedure	
Device used	34
Approach	37
Location	38
Orientation	39
Filter type and orientation	39
Filter orientation and make of device	40
Technical success	42
Technical success and type of device	42
Technical success and device	43
Post-procedure outcomes	44
Post-procedure complications and type of device	44
Post-procedure outcome and device	46
Any post-procedure complication	46
Filter complications	48
Filter complication detail	49
Post-filter placement DVT	51



Post-filter placement PE	52
Other complications	53
Retrieval	
Retrieval attempted	56
Retrieval of temporary placements by centre	57
Retrieval success	58
Duration of implant and make of device	58
Retrieval success and duration of implant	59
Retrieval success and device	60
Retrieval success and centre	61
Retrieval success and consultant	62
Retrieval success and orientation	63
Retrieval complications	64
Retrieval complications and device	64
Retrieval complications and duration of insertion	65
Long-term outcomes	
Entry of follow up data	68
Filter complications	69
Migration	69
Perforation	69
Deep vein thrombosis	70
DVT and filter retrieval	70
DVT and device	71
Pulmonary embolus	72
PE and filter retrieval	72
Mortality	73
In-hospital mortality and placement intention	73
30-day mortality and placement intention	74
30-day mortality and indication	75
Long-term survival	76
Survival and placement intention	76
Survival and retrieval	77
Appendices	
Taken from the quality improvement guidelines of the CIRSE	80
References	80
The database form	81





Background



Background

Deep vein thrombosis (DVT) is the formation of blood clots in the veins of the leg. Prevention of DVT is a high priority of the Department of Health in England, particularly in patients undergoing hospital treatment. Patients who develop DVT are potentially at risk of death if large clots travel to the heart and lungs (pulmonary embolism or PE, Fig. 1). DVT can usually be treated successfully by the use of blood thinning drugs (anticoagulation). These drugs are usually effective in preventing PE. Sometimes the drugs are ineffective or cannot be used in patients due to various risk factors. In these circumstances an alternative way of stopping clots going to the lungs is required. This is where inferior vena cava (IVC) filters might be used.



Figure 1
Pulmonary embolism

IVC filters

Most IVC filters look a bit like the metal struts of an umbrella, without the fabric (Fig. 2.a-2.d).

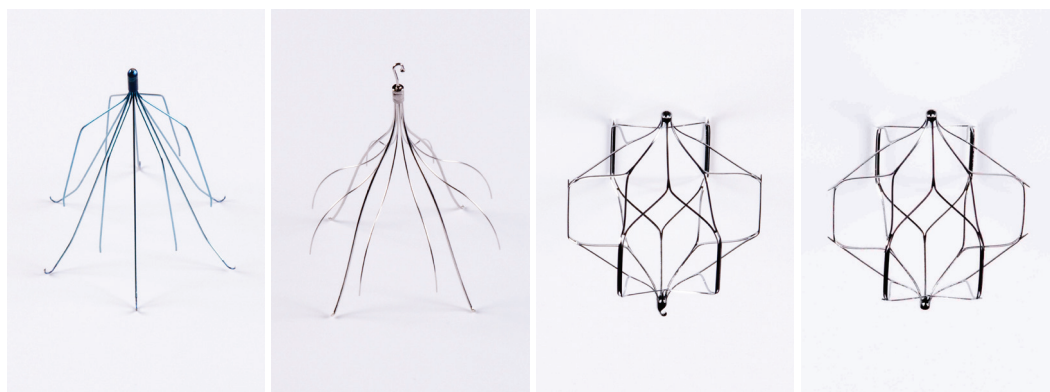


Figure 2
Various models of filters

a. Bard G2®

b. Celect™

c. Cordis OptEase®

d. Cordis TrapEase®

They can be placed inside the main vein that takes blood back to the heart from the lower body and legs, called the inferior vena cava (IVC; Fig. 3). Filters are designed to trap large clots preventing migration to the heart and potentially saving the patient's life. IVC filters have evolved over the last 40 years. The early filters (Mobin-Uddin filter) required surgery because of their large size to allow insertion. Over time they have become much smaller in size and can be placed directly through a 2 mm diameter tube inserted through a small nick in the skin without the use of surgery. They can be put in from either veins in the neck (jugular approach) or the groin (femoral approach) and some are small enough to be put in through the small veins in the arms.

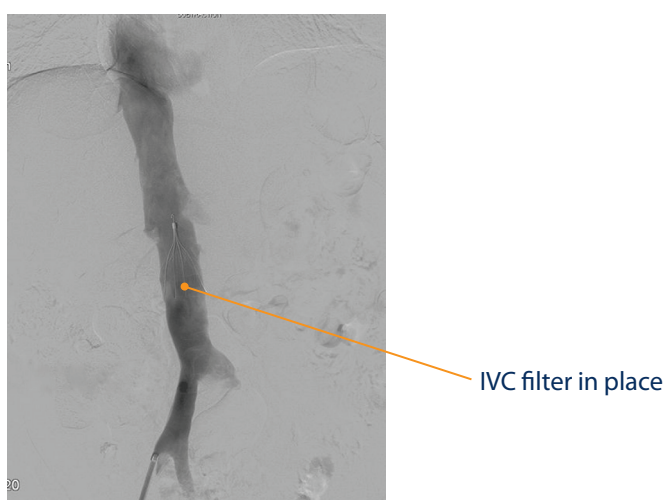


Figure 3
IVC filter in place

The evidence for benefit from caval filters over routine anticoagulation for the prevention of PE is weak. There is only one randomised controlled trial (Decousus, PREPIC) comparing IVC filter with standard anticoagulation. This study showed a small reduction in the rate of recurrent PE, but a higher rate of recurrent leg vein thrombosis in those patients that received a filter compared with those that did not. There was no difference in overall mortality.

The conclusion of this study was that filter placement is not beneficial for most patients with DVT or PE. Hence the restriction of caval filters to certain sub-groups considered to be at especially high risk. A full list of current indications based on the Cardiovascular and Interventional Radiology Society of Europe (CIRSE) guidelines is in the appendix of this report.

Types of IVC filter

There are broadly two types of filter: permanent filters are not designed to be removed; an example is the Cordis TrapEase filter (Fig. 2d), which has barbs to prevent migration either up or down, and no hook for a retrieval snare. Retrievable filters are designed so that they can be taken out again once it is felt that patient is no longer of significant risk of PE, but can be left in place permanently if necessary. Examples include the Bard G2 (Fig. 2a), the Cook Celest (Fig. 2b) and the Cordis OptEase (Fig. 2c). It is felt that removing these filters after a period of a few weeks or months might reduce some of the complications that can develop with filters left in permanently, such as blocking of the IVC (resulting in leg swelling) or perforation of the wall of the IVC by the filter struts (resulting in damage to various adjacent structures). There has been an increase in the use of retrievable filters over the last decade.

The way that filters are placed is identical for retrievable and permanent filters. The retrievable filters are removed at a later separate procedure, by collapsing the filter down into a small tube under local anaesthetic. For retrieval, the apex of the Bard G2 filter is captured in a collapsible cone introduced *via* the jugular vein. The Cook Celest and the Cordis OptEase have hooks (at apex or base) for capture using a snare and are retrieved *via* jugular or femoral route respectively. The technique for removal is relatively straightforward in most patients, but can be difficult if the filter is too tilted or has penetrated the IVC, and in such circumstances it may not be possible to remove the filter. If filters are left for a long period of time they can become incorporated into the wall of the IVC and it may not be possible to remove them safely.

The Inferior Vena Cava Filter Registry

Data on the utilisation of inferior vena cava filters within the United Kingdom are currently limited, including the use of retrievable filters. There are no data on how many of the retrievable filters are actually being taken out, nor on the complications of filter placement and retrieval. In order to answer these questions the British Society of Interventional Radiology instituted an internet-based registry in January 2008, and the data were submitted on line. The primary aim of this IVC filter registry was to assess current practice in the utilisation of IVC filters in the United Kingdom. The secondary aim was to examine outcomes for this group of patients, in particular complications of the insertion procedure, complications whilst the filter is in place and the success rate of retrieval.



A note on the conventions used throughout this report

There are a number of conventions used in the report in an attempt to ensure that the data are presented in a simple and consistent way. These conventions relate largely to the tables and the graphs, and some of these conventions are outlined below.

The specifics of the data used in any particular analysis are made clear in the accompanying text, table or chart. For example, many analyses sub-divide the data on the basis of placement intention, and the titles for both tables and charts will reflect this fact.

Conventions used in tables

On the whole, unless otherwise stated, the tables and charts in this report record the number of procedures (see the example below, which is a modified version of the table presented on page 39).

Filter orientation and type of device

		Type of device			
		Retrievable	Permanent	Unspecified	All
Filter orientation	Centralised	804	94	19	917
	Tilted	164	4	3	171
	Apex abutting caval wall	41	5	1	47
	Unspecified	81	23	16	120
	All	1,090	126	39	1,255

Each table has a short title that is intended to provide information on the subset from which the data have been drawn, such as the patient's gender or particular operation sub-grouping under examination.

The numbers in each table are colour-coded so that entries with complete data for all of the components under consideration (in this example both filter orientation and type of device) are shown in regular black text. If one or more of the database questions under analysis is blank, the data are reported as **unspecified** in red text. The totals for both rows and columns are highlighted as emboldened text.

Some tables record percentage values; in such cases this is made clear by the use of an appropriate title within the table and a % symbol after the numeric value.

Rows and columns within tables have been ordered so that they are either in ascending order (age at procedure: <20, 20-24, 25-29, 30-34, 35-39, etc.; post-procedure stay 0, 1, 2, 3, >3 days; etc.) or with negative response options first (No; None) followed by positive response options (Yes; One, Two, etc.).

Row and column titles are as detailed as possible within the confines of the space available on the page. Where a title in either a row or a column is not as detailed as the authors would have liked, then footnotes have been added to provide clarification.

There are some charts in the report that are not accompanied by data in a tabular format. In such cases the tables are omitted for one of a number of reasons:

- insufficient space on the page to accommodate both the table and graph.
- there would be more rows and /or columns of data than could reasonably be accommodated on the page (for example, Kaplan-Meier curves).
- the tabular data had already been presented elsewhere in the report.



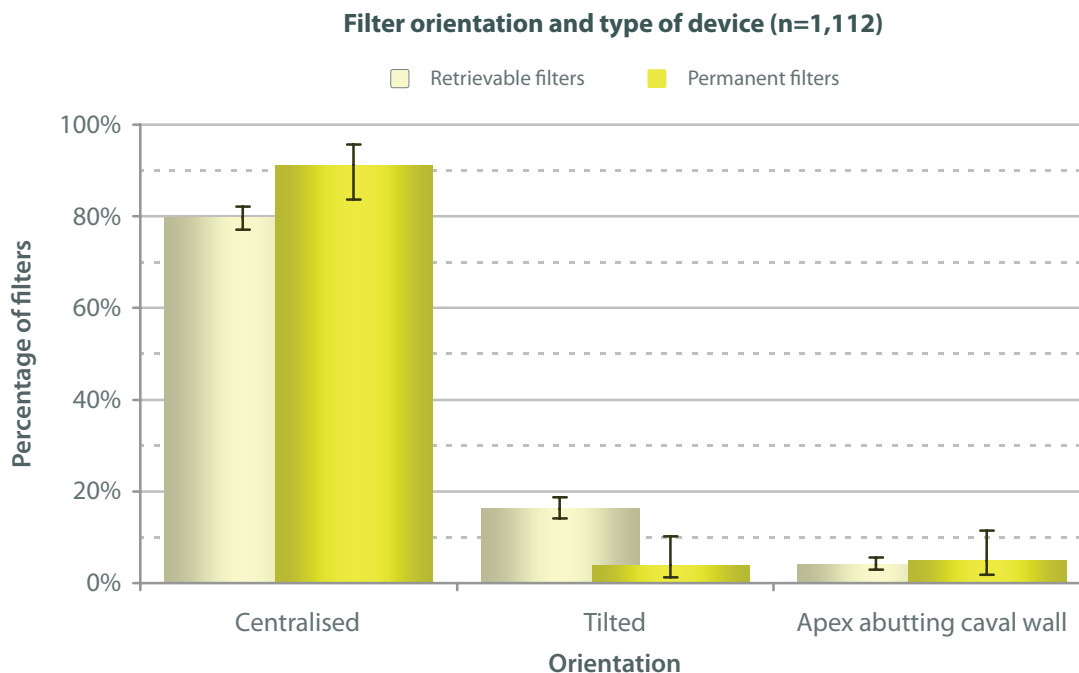
Conventions used in graphs

The basic principles applied when preparing graphs for the First UK IVC Filter Registry Report were based, as far as possible, upon William S. Cleveland's book *The elements of graphing data*¹. This book details both best practice and the theoretical bases that underlie these practices, demonstrating that there are sound, scientific reasons for plotting charts in particular ways.

Counts: The counts (shown in parentheses at the end of each graph's title as n=) associated with each graph can be affected by a number of independent factors and will therefore vary from chapter to chapter and from page to page. Most obviously, many of the charts in this report are graphic representations of results for a particular group (or subset) extracted from the database, such as temporary filter placements. This clearly restricts the total number of database-entries available for any such analysis.

In addition to this, some entries within the group under consideration have data missing in one or more of the database questions under examination (reported as unspecified in the tables); all entries with missing data are excluded from the analysis used to generate the graph because they do not add any useful information.

For example, in the graph on page 39 (reproduced below), only the entries where both the filter orientation and type of device are known are included in the analysis; this comes to 1,112 patient-entries (804 + 164 + 41 + 94 + 4 + 5; the 143 entries with unspecified data are excluded from the chart).



Confidence interval: In the charts prepared for this report, most of the bars plotted around rates (percentage values) represent 95% confidence intervals². The width of the confidence interval provides some idea of how certain we can be about the calculated rate of an event or occurrence. If the intervals around two rates do not overlap, then we can say, with the specified level of confidence, that these rates are different; however, if the bars do overlap, we cannot make such an assertion.

Bars around averaged values (such as patients' age, post-operative length-of-stay, etc.) are classical standard error bars or 95% confidence intervals; they give some idea of the spread of the data around the calculated average. In some analyses that employ these error bars there may be insufficient data to legitimately calculate the standard error around the average for each sub-group under analysis; rather than entirely exclude these low-volume sub-groups from the chart their arithmetic average would be plotted without error bars. Such averages without error bars are valid in the sense that they truly represent the data submitted; however, they should not to be taken as definitive and therefore it is recommended that such values are viewed with extra caution.

1. Cleveland WS. *The elements of graphing data*. 1985, 1994. Hobart Press, Summit, New Jersey, USA.
2. Wilson EB. Probable inference, the law of succession, and statistical inference. *Journal of American Statistical Association*. 1927; **22**: 209-212





Pre-procedure data



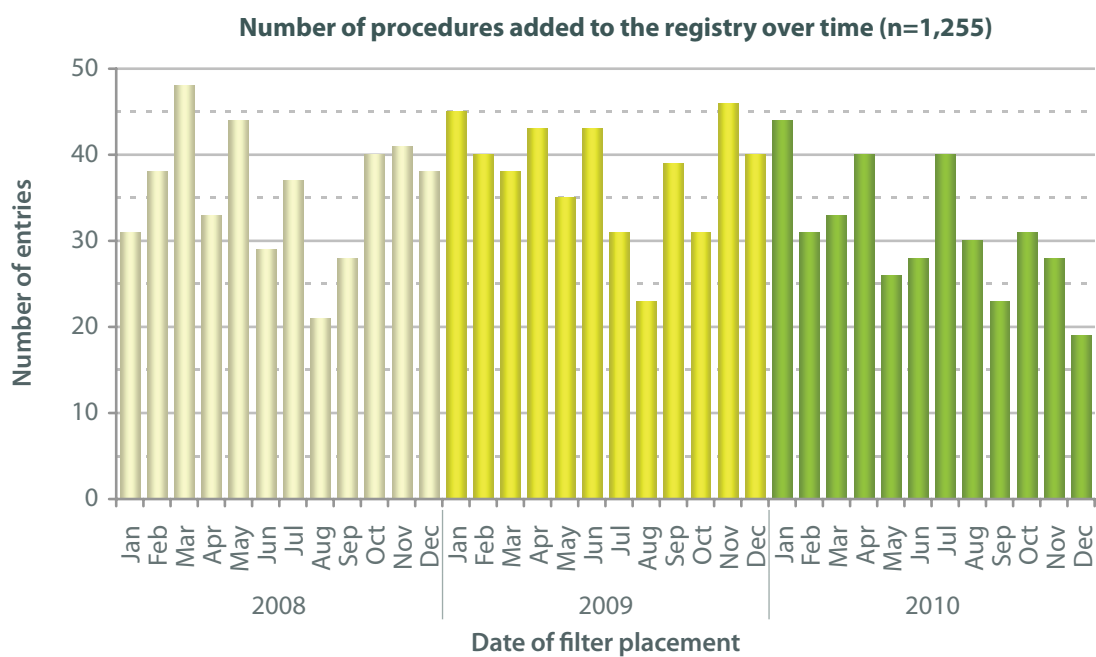
BSIR Inferior Vena Cava Filter Registry First IVC Filter Registry Report 2011

Pre-procedure data

Data acquisition

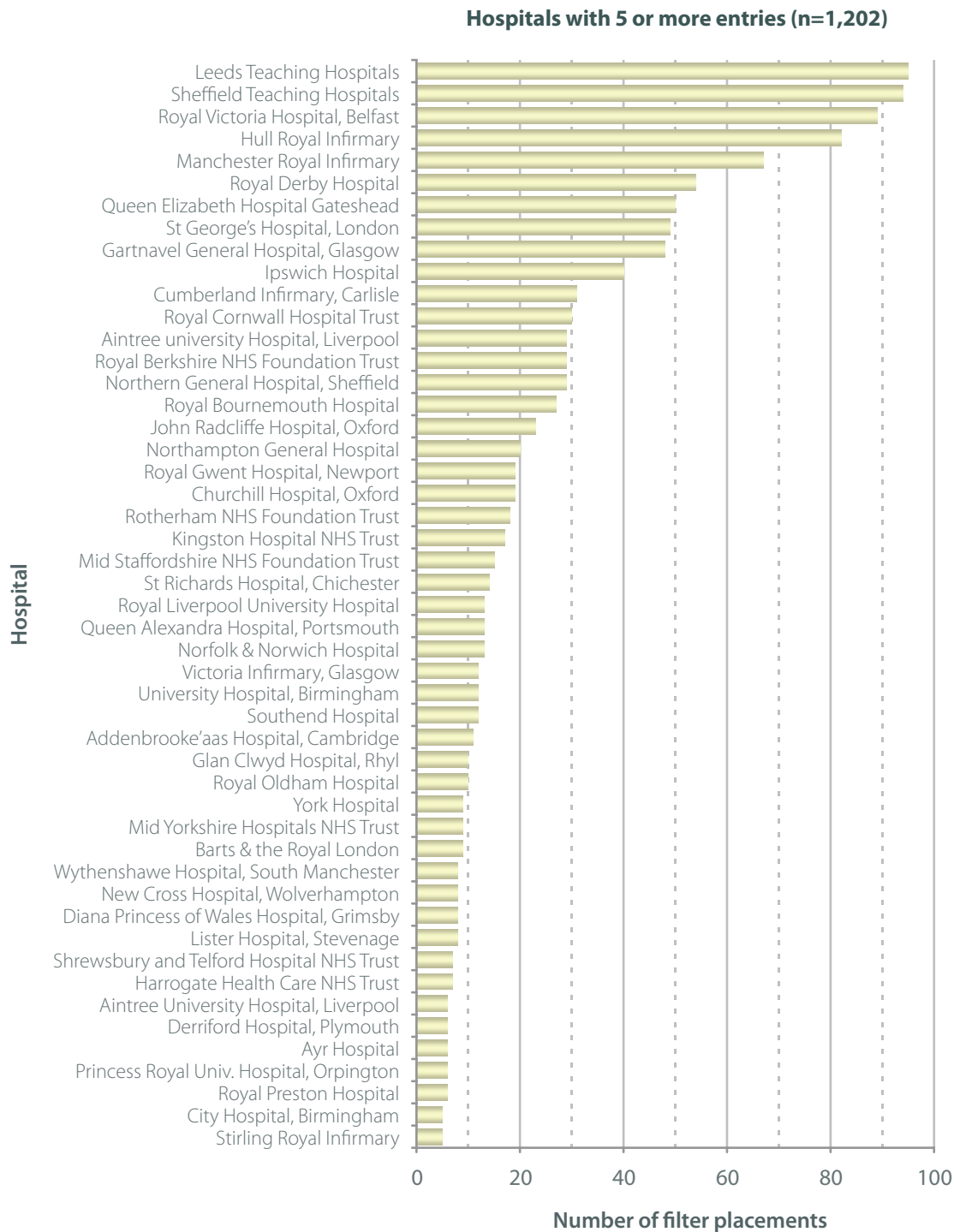
This report is based on 1,255 filter implantations dated January 2008 to December 2010.

Pre-procedure data





Contributing hospitals



Pre-procedure data

- 4 entries: Wexham Park Hospital, Slough; West Suffolk NHS Trust; Torbay Hospital; Royal Bolton Hospital; Colchester General Hospital
- 3 entries: Hairmyres Hospital, East Kilbride; East Sussex Hospitals NHS Trust; Freeman Hospital, Newcastle-upon-Tyne; Leicester Royal Infirmary; Southampton General Hospital
- 2 entries: Southern General Hospital, Glasgow; Royal Surrey County Hospital, Guilford; Pinderfields Hospital, Wakefield; Papworth Hospital
- 1 entry: University Hospital Wales, Cardiff; Medway Maritime Hospital, Gillingham; Frimley Park Hospital, Surrey; Altnagelvin Area Hospital; North Bristol NHS Trust



Patient demographics

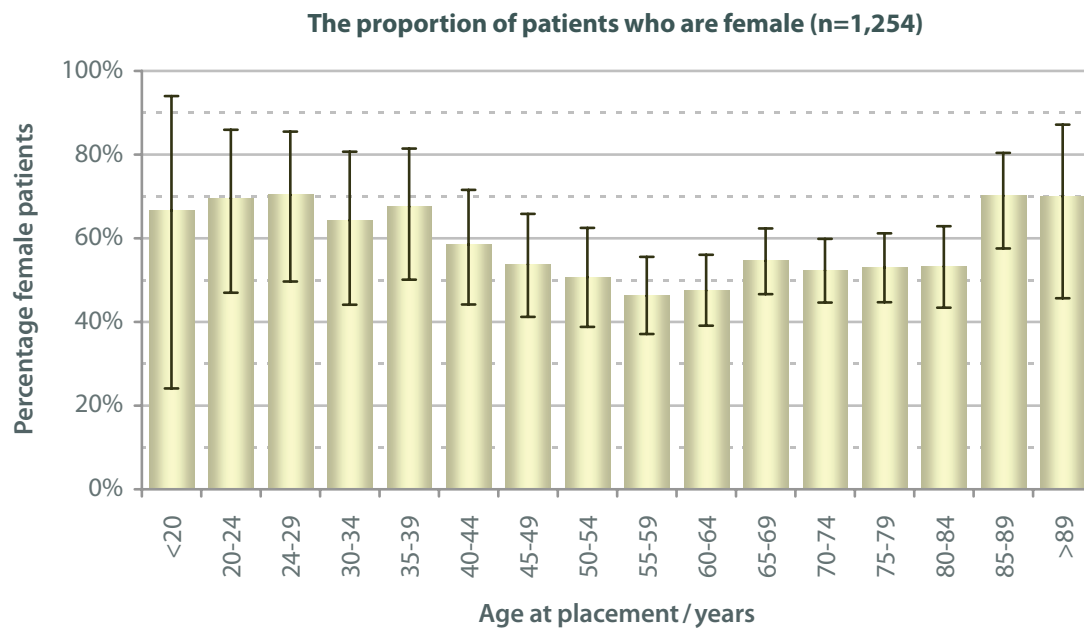
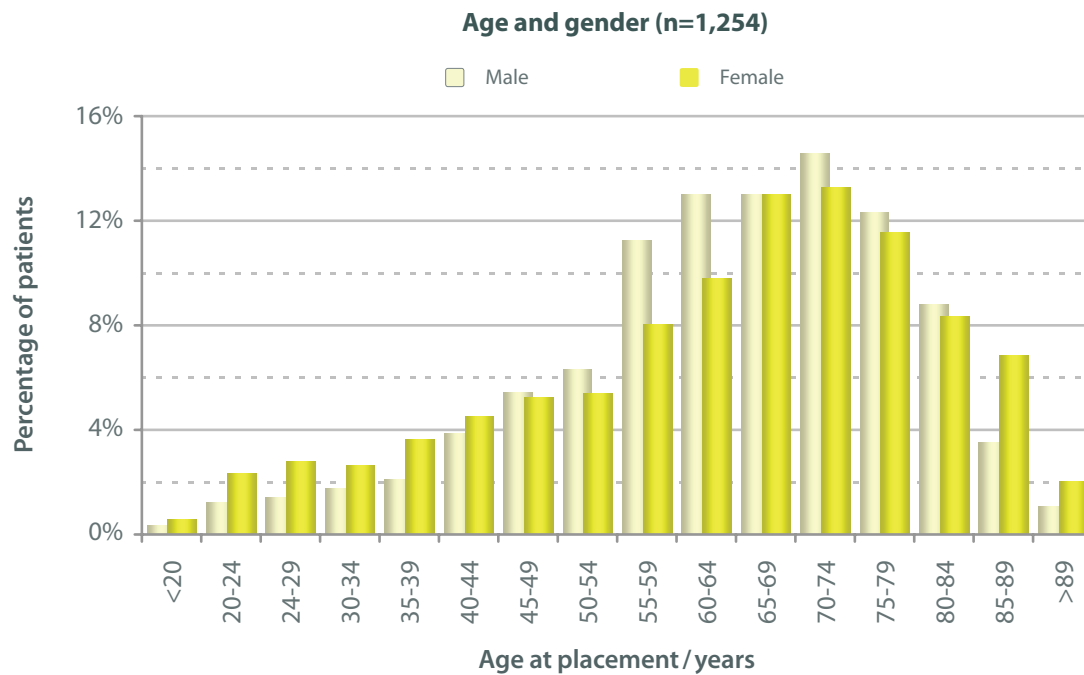
Age and gender

The peak in age distribution, irrespective of gender, is at 70-74 years; there is, however, no statistically significant difference in age distributions between the genders. The proportion of female patients is at its highest in the under 40-year-olds, which might be related to the known risk factors for DVT of oral contraceptive use and pregnancy. There are relatively more men than women in the 55-64 year-old age group, and a preponderance of women in the very oldest age groups, which is a reflection of the greater longevity of women.

Looking in more detail at the age and gender distributions for each indication, there is no evidence of any statistically significant differences.

Age and gender distributions

		Gender				
		Male	Female	Unspecified	All	Proportion female
Age at placement / years	<20	2	4	0	6	66.7%
	20-24	7	16	0	23	69.6%
	25-29	8	19	0	27	70.4%
	30-34	10	18	0	28	64.3%
	35-39	12	25	0	37	67.6%
	40-44	22	31	0	53	58.5%
	45-49	31	36	0	67	53.7%
	50-54	36	37	0	73	50.7%
	55-59	64	55	0	119	46.2%
	60-64	74	67	0	141	47.5%
	65-69	74	89	0	163	54.6%
	70-74	83	91	0	174	52.3%
	75-79	70	79	0	149	53.0%
	80-84	50	57	0	107	53.3%
	85-89	20	47	0	67	70.1%
	>89	6	14	0	20	70.0%
	Unspecified	0	1	0	1	100.0%
	All	569	686	0	1,255	54.7%





Indication

Indication for placement

The most commonly-recorded indication for filter placement is *Pre-operative with acute DVT / PE*, followed closely by *PE with contra-indication to anticoagulation*.

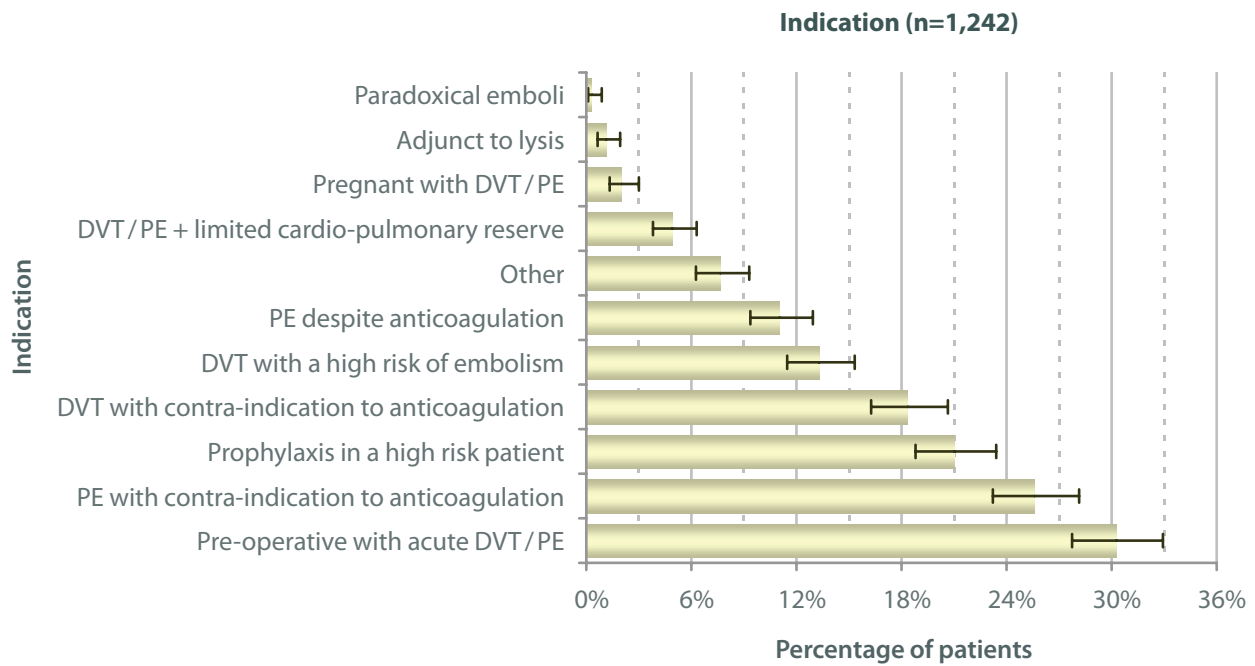
Most filters were placed in accordance with *accepted* or *additional* indications according to CIRSE Guidelines (see appendix).

Of the 95 patient-entries with an *Other* indication, only 34 have this as their sole indication and most of these can be accommodated in the recognised list of indications. Of the 5 that cannot be reassigned, *Progression of DVT despite anticoagulation* comprises the majority.

Indication

		Data	
		Count	Proportion
Indication	PE despite anticoagulation	137	11.0%
	PE with contra-indication to anticoagulation	318	25.6%
	DVT / PE plus limited cardio-pulmonary reserve	61	4.9%
	DVT with high risk of embolism	165	13.3%
	Paradoxical emboli	4	0.3%
	DVT with contra-indication to anticoagulation	228	18.4%
	Adjunct to lysis	14	1.1%
	Prophylaxis in a high risk patient	261	21.0%
	Pre-operative with acute DVT / PE	376	30.3%
	Pregnant with DVT / PE	25	2.0%
	Other	95	7.6%
	Unspecified	13	
	Patient denominatorⁱ	1,255	

i Each patient may have more than one indication recorded, so the total number of indications may legitimately exceed the total number of patients.



Pre-procedure data



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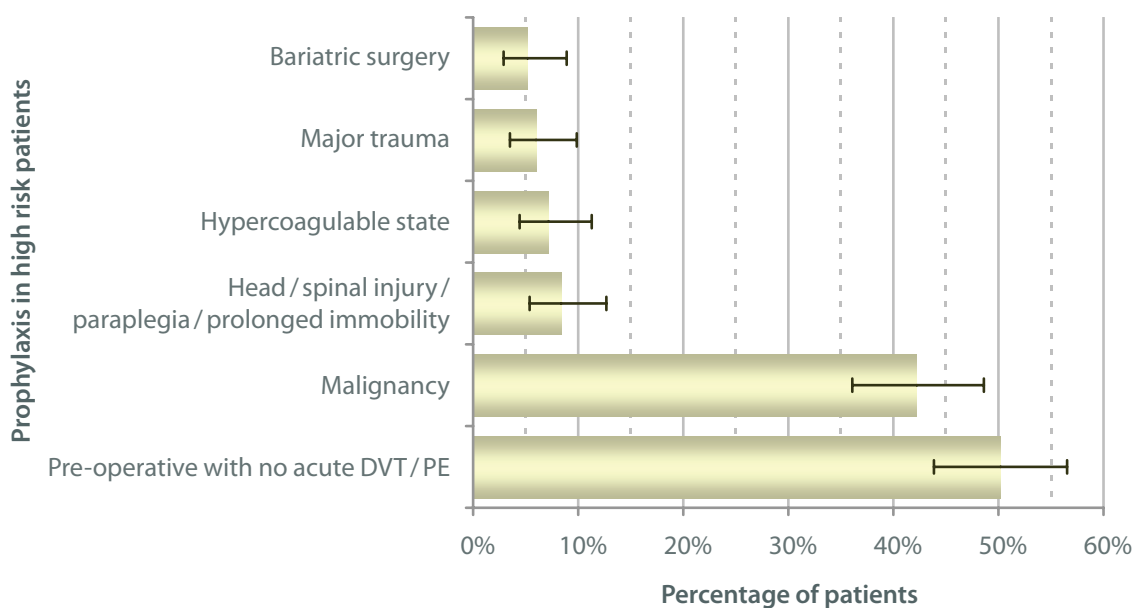
Prophylaxis in high risk patients

This includes patients with risk factors, who may or may not have known acute DVT or PE. Malignancy was the only recorded indication for filter placement in 34 patients. It is questionable whether these lie within CIRSE guidelines, under the definition of *High risk patients*.

Prophylaxis in high risk patients: details of risk category

		Data	
		Count	Proportion
Prophylaxis in high risk patients	Head / spinal injury / paraplegia / prolonged immobility	21	8.4%
	Major trauma	15	6.0%
	Bariatric surgery	13	5.2%
	Hypercoagulable state	18	7.2%
	Malignancy	106	42.2%
	Pre-operative with no acute DVT / PE	126	50.2%
	Unspecified	10	
	All	261	

Prophylaxis in high risk patients (n=251)





Placement intention

A chi-squared analysis of trend over time for filter placements intended to be temporary *versus* non-temporary shows a significant trend (χ^2 analysis of trend over time; $p=0.014$). Over the life-span of the registry there was a trend for increasing use of temporary filter placements. This may indicate an increasing reluctance to leave filters permanently, or an increasing confidence in the retrievable devices.

Not surprisingly, 90% of placements in the 20-29 year-old age group were intended to be temporary compared with 20% in the 80-89 year-old age group, reflecting clinicians' reluctance to leave foreign materials permanently in younger patients.

Convertible filters are recently introduced devices that can be changed from a *filter* configuration to a *stent*, once the filtering capability is no longer required. Following the introduction of *convertible* filters to the United Kingdom market, contributors were given the opportunity to record this as an intention. In the event, no convertible filters were used, so any recorded as such are errors.

Placement intention over time

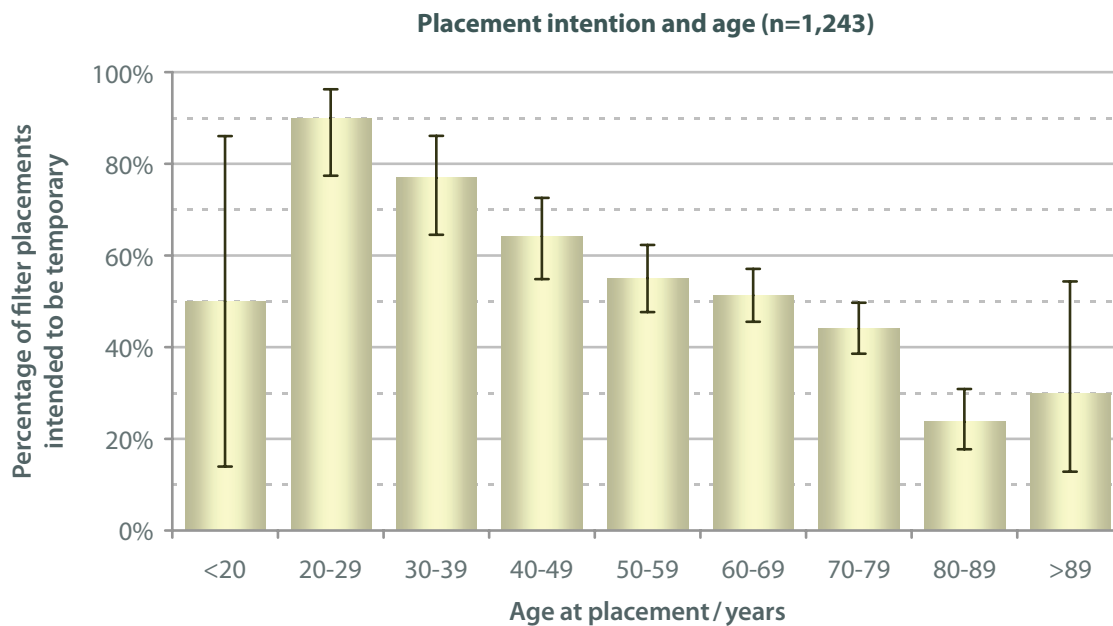
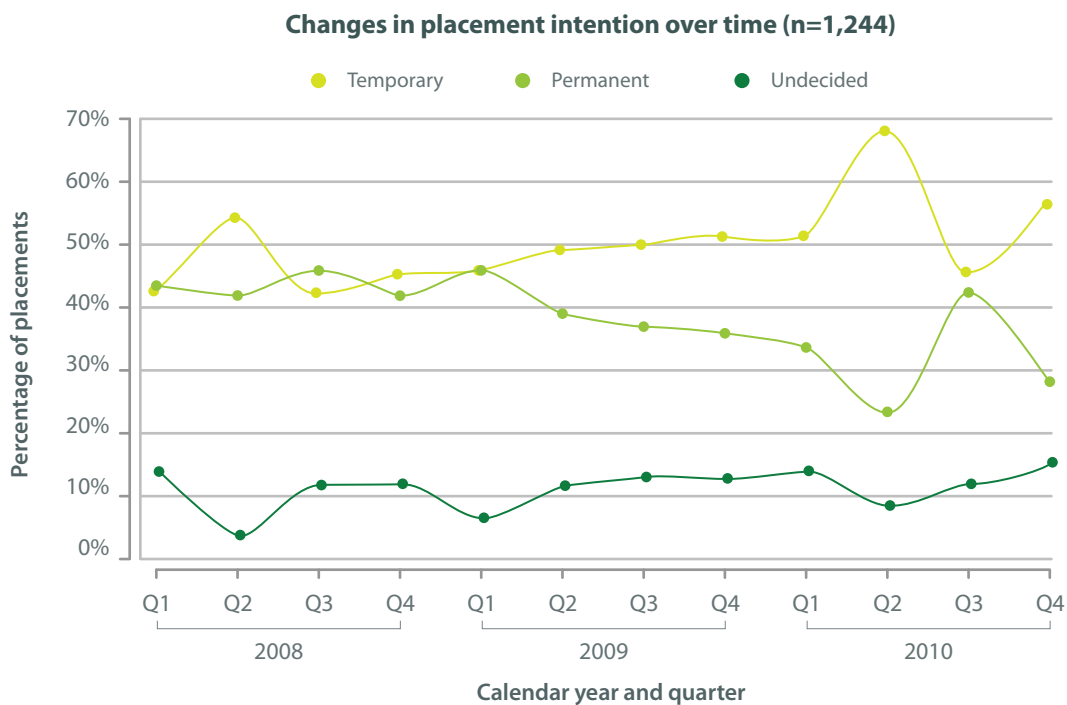
			Intention						
			Temporary	Permanent	Conversion	Undecided	Unspecified	All	Proportion temporary
Period: calendar year & quarter ⁱ	2008	Q1	49	50	0	16	2	117	42.6%
		Q2	57	44	0	4	1	106	54.3%
		Q3	36	39	0	10	1	86	42.4%
		Q4	53	49	1	14	2	119	45.3%
	2009	Q1	56	56	2	8	1	123	45.9%
		Q2	59	47	0	14	1	121	49.2%
		Q3	46	34	0	12	1	93	50.0%
		Q4	60	42	0	15	0	117	51.3%
	2010	Q1	55	36	1	15	1	108	51.4%
		Q2	64	22	0	8	0	94	68.1%
		Q3	42	39	0	11	1	93	45.7%
		Q4	44	22	0	12	0	78	56.4%
All			621	480	4	139	11	1,255	49.9%

i Q1 → January-March; Q2 → April-June; Q3 → July-September; Q4 → October-December.



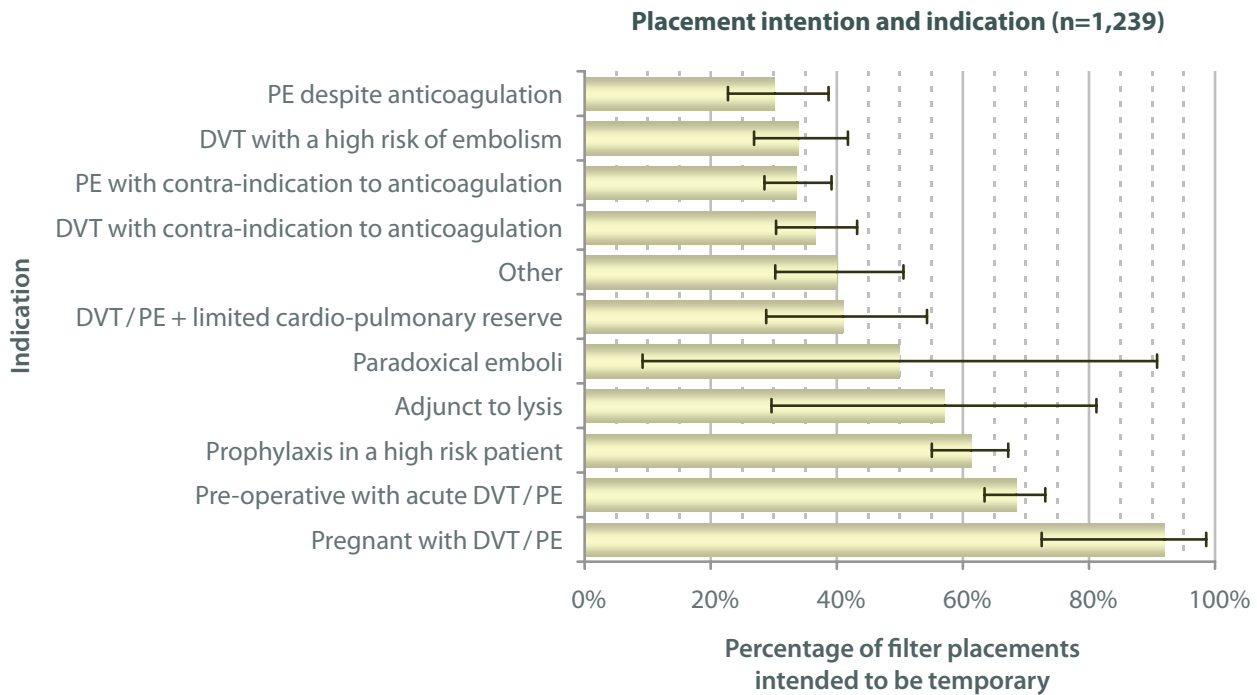
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Pre-procedure data





The chart below shows the relationship between indication and placement intention. Those with presumed life-long risk were more likely to have a permanent filter. The great majority of filters placed during pregnancy were intended for removal. Likewise, where there is clearly a short-term risk, such as pre-operative patients with acute DVT / PE, the intention was for short-term filter placement in the majority of cases.



Pre-procedure data





The procedure



The procedure

Device used

Filters can broadly be divided into two groups: retrievable and permanent. Instructions for use state that retrievable can be left in place permanently if desired. As a consequence even where the intention was to leave the filter in place permanently, a retrievable filter was utilised in the majority of cases (341 of 468 filters intended for permanent placement; 73.3%). This indicates that operators have confidence in the permanent deployment of retrievable filters.

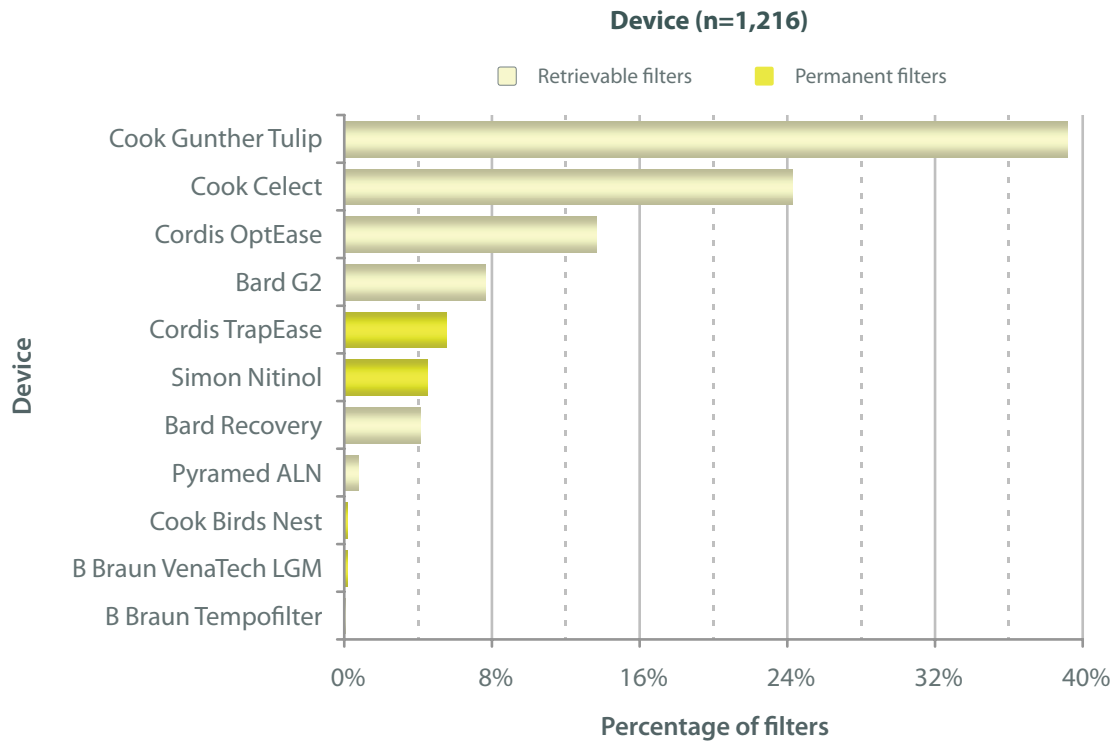
The Gunther Tulip filter has been available since 1992, and clearly remains the most commonly placed IVC filter, despite the introduction of a number of new filters to the market. The Cook Celect filter, an evolution of the Tulip filter, is the second most commonly placed device. Together, these two filters account for 63.4% of all the filter placements recorded in the Registry.

Filter device

			Data	
			Count	Proportion
Device	Retrievable	B Braun Tempofilter	1	0.1%
		Bard G2	93	7.6%
		Bard Recovery	50	4.1%
		Cook Celect	295	24.3%
		Cook Gunther Tulip	476	39.1%
		Cordis OptEase	166	13.7%
		Pyramed ALN	9	0.7%
	Permanent	B Braun VenaTech LGM	2	0.2%
		Cook Birds Nest	2	0.2%
		Cordis TrapEase	67	5.5%
		Simon Nitinol	55	4.5%
	Unspecified		39	
	All		1,255	

Disclaimer

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Disclaimer

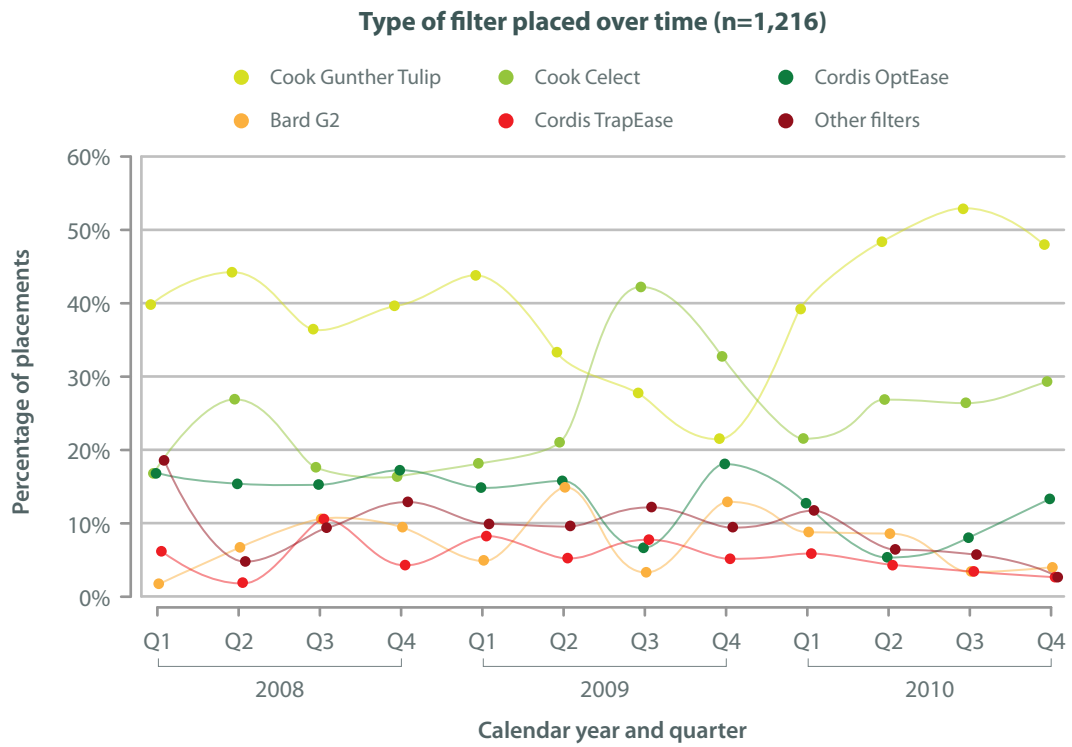
Analyses of the type of device are not intended to be representative of market share as the registry is not currently capturing all procedures performed in the United Kingdom.



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There is a statistically significant trend for a proportionate increase in the use of the Celect filter over the lifetime of the Registry.

The procedure



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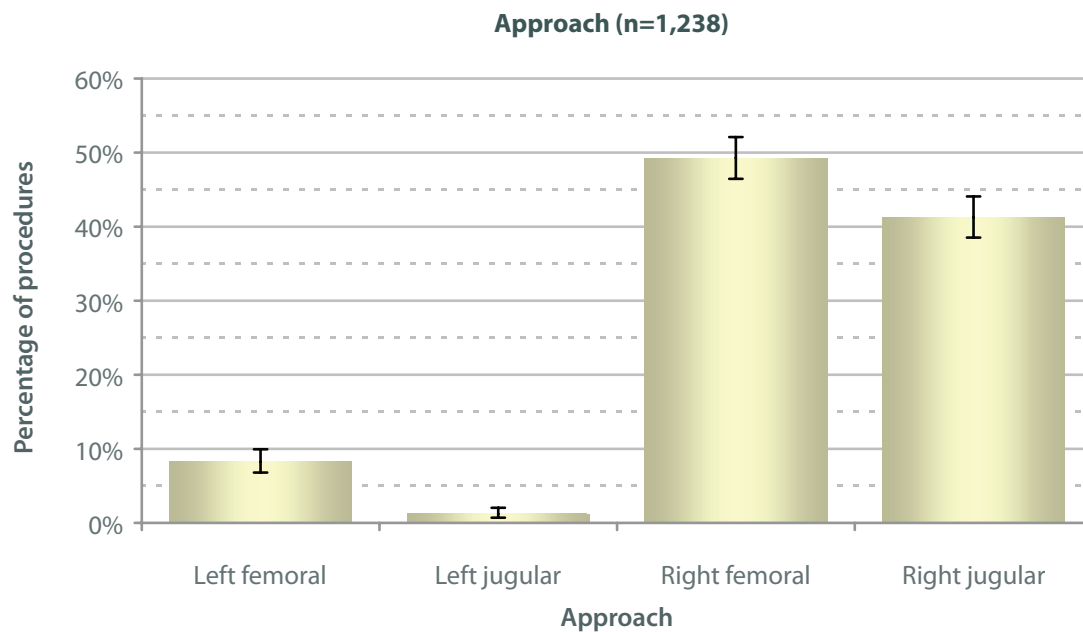


Approach

Most filters can be deployed using either a jugular or femoral approach. The majority of procedures involved the use of the right femoral or right jugular approach. The left jugular approach was very rarely used. Almost two-thirds of procedures were completed within 30 minutes. Significantly more procedures took over 30 minutes when using the left femoral versus the right jugular approach (2x2 contingency table; $p=0.018$).

Approach

		Data	
		Count	Proportion
Approach	Left femoral	102	8.2%
	Left jugular	15	1.2%
	Right femoral	610	49.3%
	Right jugular	511	41.3%
	Unspecified	17	
	All	1,255	





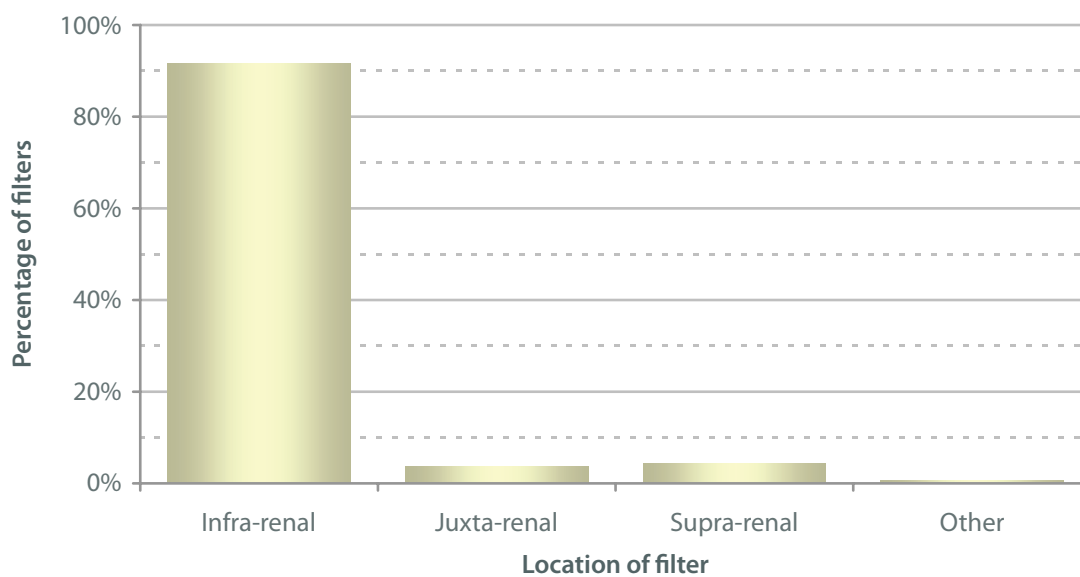
Location

Predictably, the vast majority of filters are placed in an infra-renal or juxta-renal location. Of the 53 supra-renal filter placements, 27 were for IVC thrombosis and 13 for pregnancy. There is no clear reason for choosing the supra-renal location in 7 and there are missing data in 6.

Location

		Data	
		Count	Proportion
Location	Infra-renal IVC	1,128	91.6%
	Juxta-renal IVC	44	3.6%
	Supra-renal IVC	53	4.3%
	Other	7	0.6%
	Unspecified	23	
	All	1,255	

Filter location (n=1,232)





Orientation

Filter type and orientation

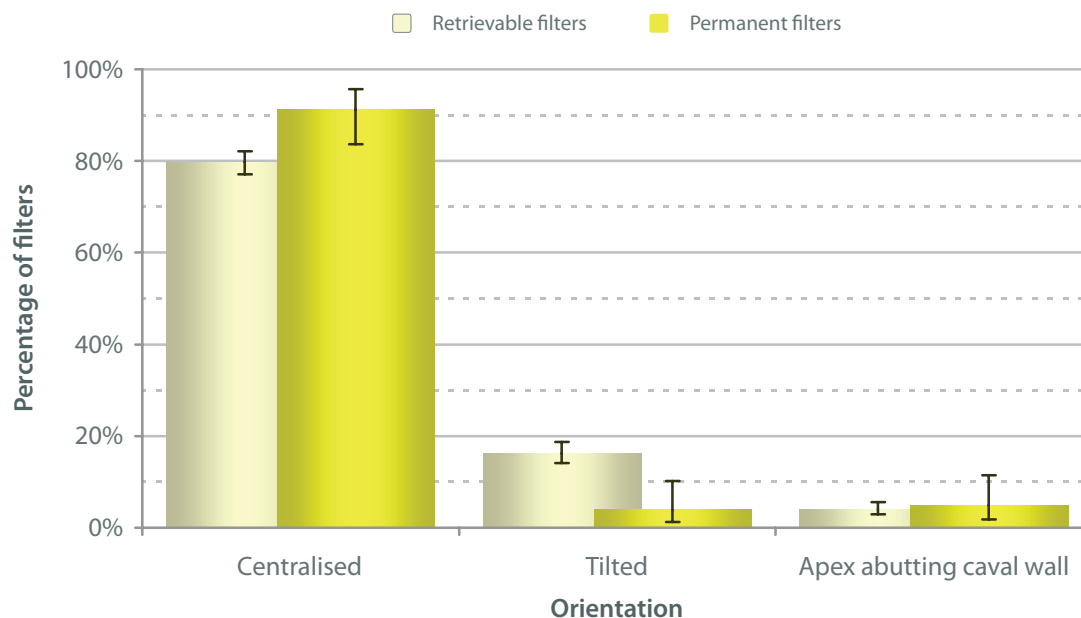
Most filters are intended to be located so that the apex lies centrally within the vena cava and some have design features to promote centring. The VenaTech Braun LGM filter has a number of parallel struts that lie along the caval wall to ensure centring. No tilting was observed with the few that were reported. The Cordis filters also have parallel struts, but these are less rigid, so distortion and tilting can occur. Tilting was observed more frequently with the OptEase than the TrapEase. This may be explained by the difference in number and orientation of the anchoring bars on the TrapEase. Tilting is more frequently observed with the Cook filters which have a conical shape.

Tilting may occur at the moment of release of the filter from the delivery system if the delivery system is angulated in relation to the axis of the cava. It may also occur during detachment of the apical hook from the delivery system after jugular deployment of the Cook filters.

Filter orientation and type of device

		Type of device			
		Retrievable	Permanent	Unspecified	All
Filter orientation	Centralised	804	94	19	917
	Tilted	164	4	3	171
	Apex abutting caval wall	41	5	1	47
	Unspecified	81	23	16	120
	All	1,090	126	39	1,255

Filter orientation and type of device (n=1,112)





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Filter orientation and make of device

The Cook Gunther Tulip and Celest filters were associated with tilting, or apex abutting the caval wall, in more than 20% of placements. Tilting was less frequently reported with the Cordis TrapEase and OptEase and the Bard G2 device. Tulip and Celest filters deployed *via* the left femoral approach were significantly less likely to be centralised than those deployed *via* the right femoral approach (2x2 contingency table; $p=0.013$) or *via* the right jugular approach (2x2 contingency table; $p=0.021$). These findings suggest that, if the right femoral approach is not available, a right jugular approach is probably preferable to a left femoral approach.

Filter device and orientation

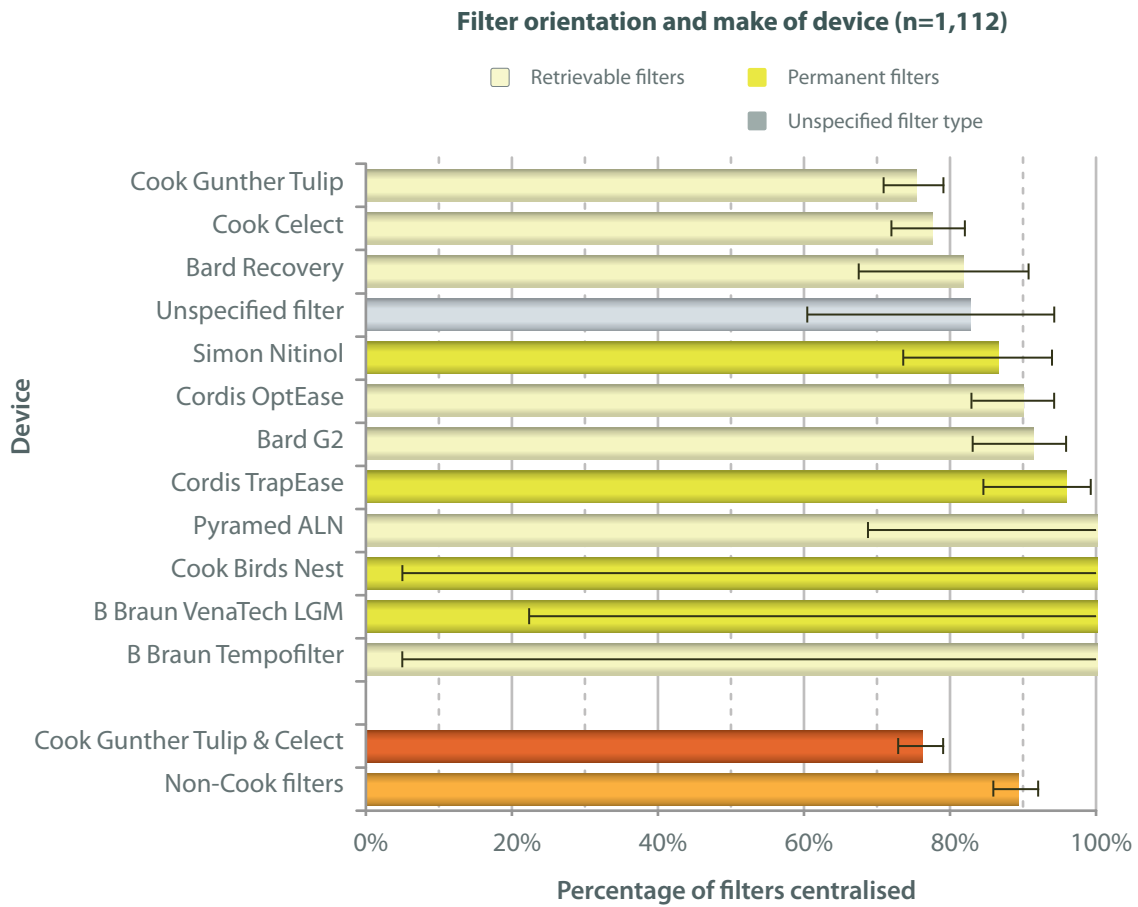
			Filter orientation				
			Centralised	Tilted	Apex abutting caval wall	Unspecified	All
Device	Retrievable	B Braun Tempofilter	1	0	0	0	1
		Bard G2	84	6	2	1	93
		Bard Recovery	40	9	0	1	50
		Cook Celest	219	50	14	12	295
		Cook Gunther Tulip	337	88	23	28	476
		Cordis OptEase	115	11	2	38	166
		Pyramed ALN	8	0	0	1	9
	Permanent	B Braun VenaTech LGM	2	0	0	0	2
		Cook Birds Nest	1	0	0	1	2
		Cordis TrapEase	46	1	1	19	67
		Simon Nitinol	45	3	4	3	55
	Unspecified		19	3	1	16	39
	All		917	171	47	120	1,255

Filter device and orientation

			Filter orientation				
			Centralised	Tilted	Apex abutting caval wall	Unspecified	All
Device	Cook Celest & Gunther Tulip		556	138	37	40	771
	Cook Birds Nest		1	0	0	1	2
	Non-Cook filters		342	30	9	64	445
	Unspecified		19	3	1	16	39
	All		917	171	47	120	1,255

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Technical success

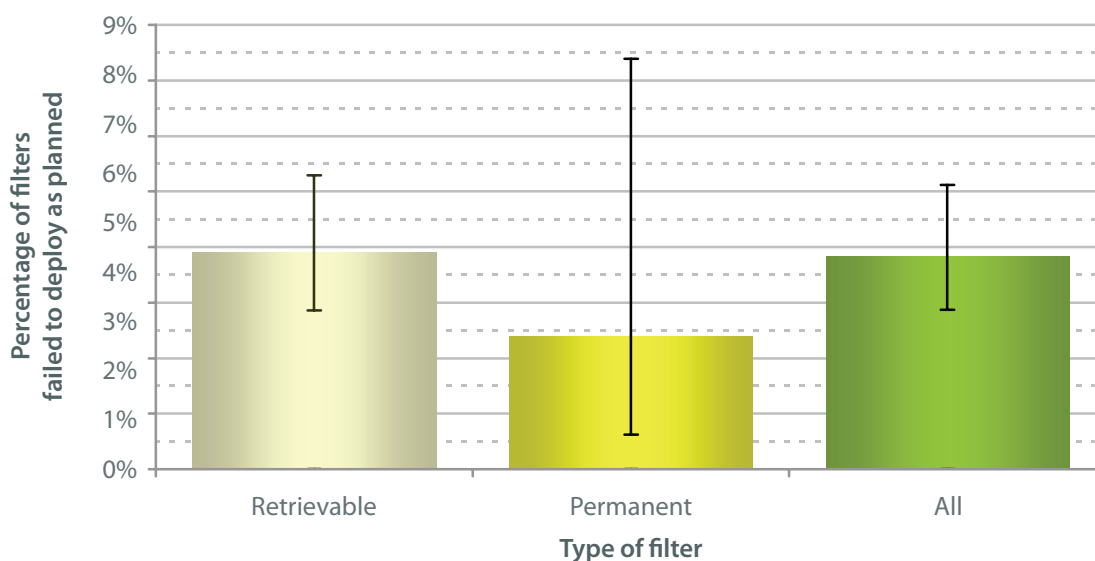
Technical success and type of device

Failure to deploy as planned occurred in 3.8% of cases (47 / 1,176). The explanation in most cases was *tilting*, sometimes due to unexpected anatomical variations. *Failure to open properly* or *Failure to deploy at the intended site* was reported in 10 cases (8 Tulip, 2 Simon Nitinol). The procedure was abandoned in only 2 cases. In one case, a Cordis OptEase device was retrieved immediately after placement because of pain. In other cases initial filter deployment resulted in extreme angulation, and further manipulation was required to locate the filter in a satisfactory orientation. The rate of failure to deploy as planned was significantly lower for Cordis (TrapEase and OptEase) filters when compared to all other filters combined.

Technical success: placement as planned and type of device

		Placement as planned			
		No	Yes	Unspecified	Failure rate & 95% CI
Type of device	Retrievable filters	42	1,033	15	3.9% (2.9-5.3%)
	Permanent filters	3	122	1	2.4% (0.6-7.4%)
	Unspecified	2	21	16	8.7% (1.5-29.5%)
	All	47	1,176	32	3.8% (2.9-5.1%)

Failure to deploy the filter as planned (n=1,223)





Technical success and device

Filter device and successful deployment

			Placement as planned			
			No	Yes	Unspecified	Failure rate & 95% CI
Device	Retrievable	B Braun Tempofilter	0	1	0	0.0% (0.0-95.0%)
		Bard G2	7	86	0	7.5% (3.3-15.4%)
		Bard Recovery	2	47	1	4.1% (0.7-15.1%)
		Cook Celect	5	283	7	1.7% (0.6-4.2%)
		Cook Gunther Tulip	27	443	6	5.7% (3.9-8.4%)
		Cordis OptEase	1	165	0	0.6% (0.0-3.8%)
	Permanent	Pyramed ALN	0	8	1	0.0% (0.0-31.2%)
		B Braun VenaTech LGM	0	2	0	0.0% (0.0-77.6%)
		Cook Birds Nest	0	2	0	0.0% (0.0-77.6%)
		Cordis TrapEase	0	66	1	0.0% (0.0-4.4%)
		Simon Nitinol	3	52	0	5.5% (1.4-16.1%)
	Unspecified		2	21	16	
	All		47	1,176	32	

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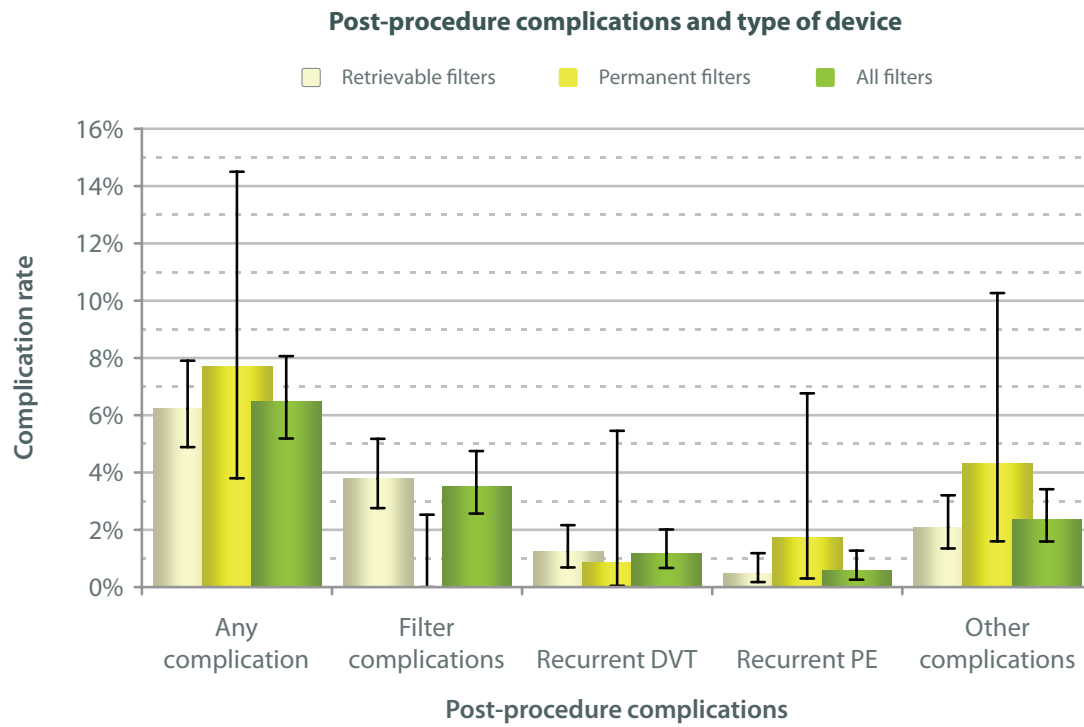
Post-procedure outcomes

Post-procedure complications and type of device

One of the concerns that the registry sought to address was whether retrievable filters inserted for permanent placement were as safe as filters specifically designed for permanent placement. A lower rate of filter-specific complications was observed with permanent than with retrievable filters, but overall complications were not statistically significantly different.

Post-procedure outcomes and type of device

			Adverse outcome			
			No	Yes	Unspecified	Rate & 95% CI
Post-procedure complications	Any post-procedure complication	Retrievable filters	993	66	31	6.2% (4.9-7.9%)
		Permanent filters	108	9	9	7.7% (3.8-14.5%)
		Unspecified	24	3	12	11.1% (2.9-30.3%)
		All	1,125	78	52	6.5% (5.2-8.1%)
	Filter complications	Retrievable filters	1,015	40	35	3.8% (2.8-5.2%)
		Permanent filters	117	0	9	0.0% (0.0-2.5%)
		Unspecified	25	2	12	7.4% (1.3-25.8%)
		All	1,157	42	56	3.5% (2.6-4.7%)
	Recurrent DVT	Retrievable filters	1,039	13	38	1.2% (0.7-2.2%)
		Permanent filters	114	1	11	0.9% (0.0-5.5%)
		Unspecified	27	0	12	0.0% (0.0-10.5%)
		All	1,180	14	61	1.2% (0.7-2.0%)
	Recurrent PE	Retrievable filters	1,036	5	49	0.5% (0.2-1.2%)
		Permanent filters	113	2	11	1.7% (0.3-6.8%)
		Unspecified	27	0	12	0.0% (0.0-10.5%)
		All	1,176	7	72	0.6% (0.3-1.3%)
	Other complications	Retrievable filters	1,029	22	39	2.1% (1.3-3.2%)
		Permanent filters	111	5	10	4.3% (1.6-10.3%)
		Unspecified	26	1	12	3.7% (0.2-20.9%)
		All	1,166	28	61	2.3% (1.6-3.4%)



Post-procedure



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Post-procedure outcome and device

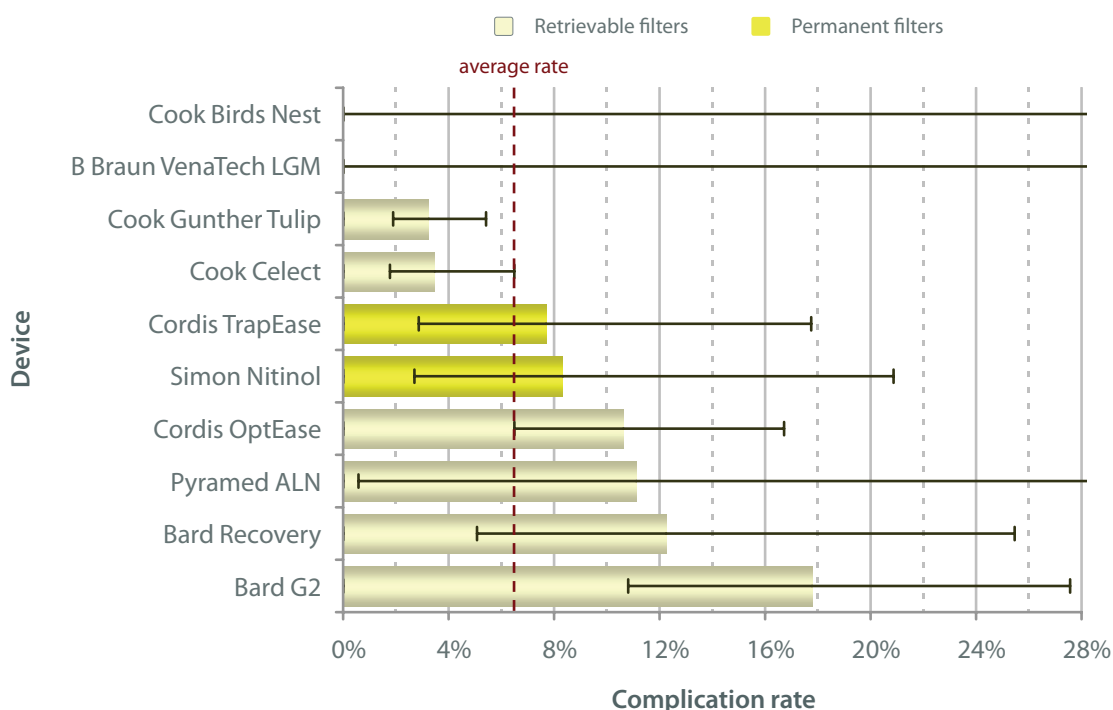
Any post-procedure complication

A funnel plot analysis of overall post-procedure complications and filter-specific complications identified the rates associated with the Bard G2 filter as lying outside 99.9% control limits (average rate = 6.4%). The outcomes for all other filter types fell within both 99.9% control limits of the funnel plot.

Filter device and successful deployment

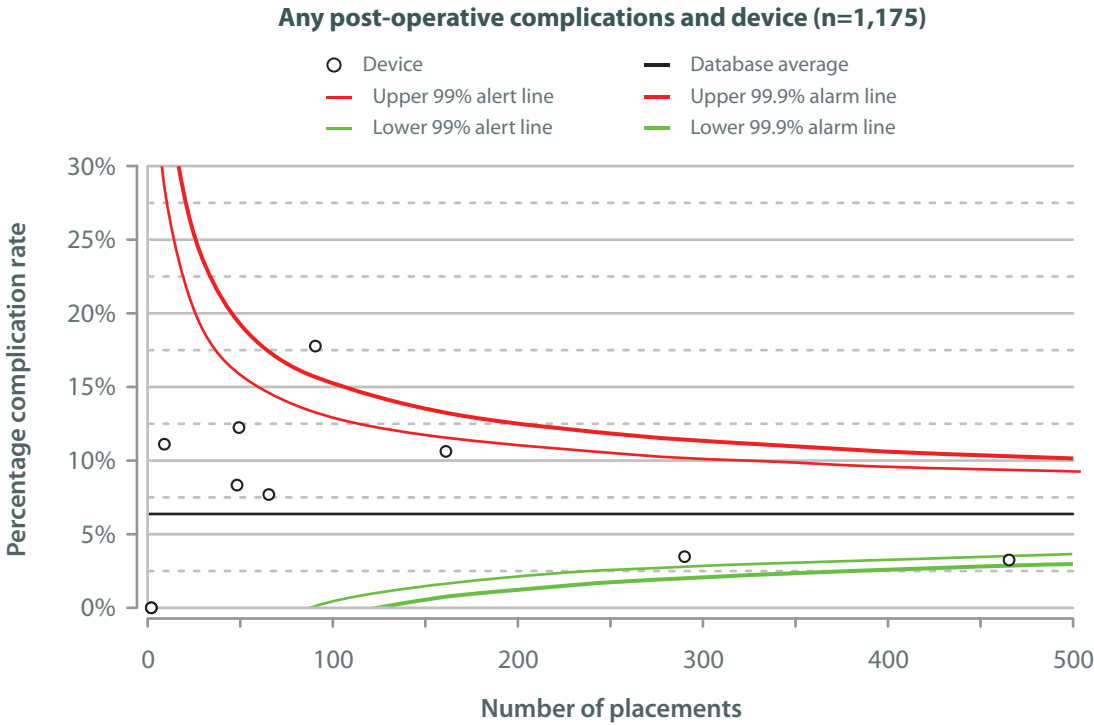
			Any complication			
			No	Yes	Unspecified	Rate & 95% CI
Device	Retrievable	B Braun Tempofilter	0	1	0	100.0% (5.0-100.0%)
		Bard G2	74	16	3	17.8% (10.8-27.6%)
		Bard Recovery	43	6	1	12.2% (5.1-25.5%)
		Cook Celect	278	10	7	3.5% (1.8-6.5%)
		Cook Gunther Tulip	447	15	14	3.2% (1.9-5.4%)
		Cordis OptEase	143	17	6	10.6% (6.5-16.7%)
		Pyramed ALN	8	1	0	11.1% (0.6-49.3%)
	Permanent	B Braun VenaTech LGM	2	0	0	0.0% (0.0-77.6%)
		Cook Birds Nest	2	0	0	0.0% (0.0-77.6%)
		Cordis TrapEase	60	5	2	7.7% (2.9-17.8%)
		Simon Nitinol	44	4	7	8.3% (2.7-20.9%)
	Unspecified		24	3	12	
	All		1,125	78	52	

Any post-operative complications and device (n=1,175)



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Post-procedure

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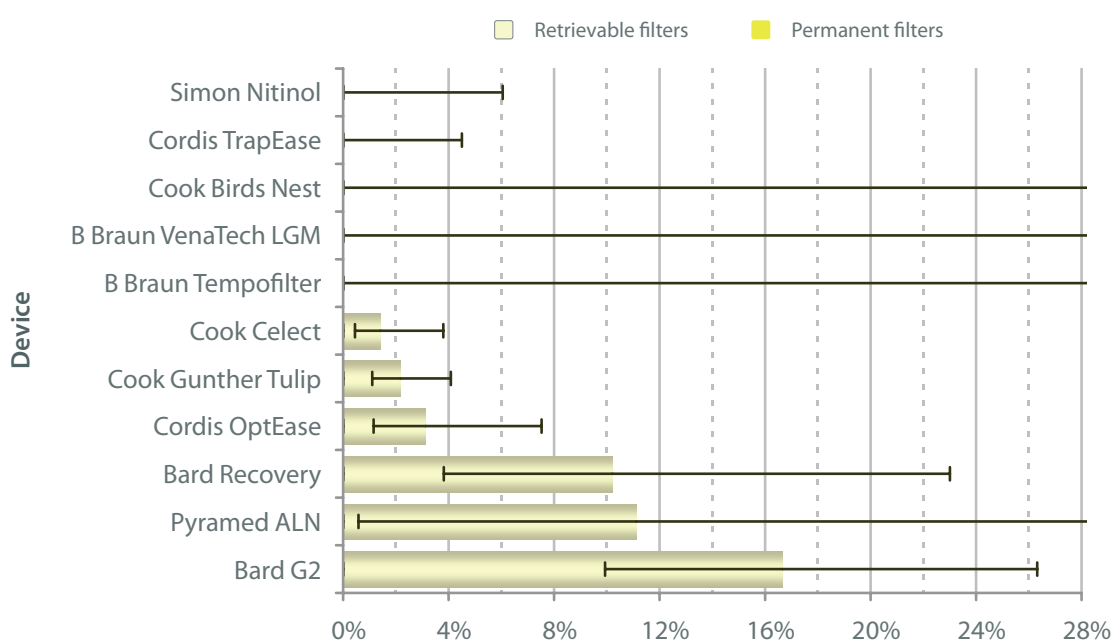
Filter complications

In general, filter complication rates are low, with an average complication rate of 3.5%. There were, however, two reported major complications involving surgical removal of the filter. Pain associated with caval perforation led to surgical removal of a Cook Celect filter in one case. A further filter (Cook Gunther Tulip) required surgical removal following penetration through the caval wall during insertion. A third filter was removed at laparotomy performed for other reasons: penetration of the caval wall was noted at surgery.

Filter device and filter complications

			Filter complications			
			No	Yes	Unspecified	Rate & 95% CI
Device	Retrievable	B Braun Tempofilter	1	0	0	0.0% (0.0-95.0%)
		Bard G2	75	15	3	16.7% (9.9-26.3%)
		Bard Recovery	44	5	1	10.2% (3.8-23.0%)
		Cook Celect	281	4	10	1.4% (0.5-3.8%)
		Cook Gunther Tulip	451	10	15	2.2% (1.1-4.1%)
		Cordis OptEase	155	5	6	3.1% (1.2-7.5%)
		Pyramed ALN	8	1	0	11.1% (0.6-49.3%)
	Permanent	B Braun VenaTech LGM	2	0	0	0.0% (0.0-77.6%)
		Cook Birds Nest	2	0	0	0.0% (0.0-77.6%)
		Cordis TrapEase	65	0	2	0.0% (0.0-4.5%)
		Simon Nitinol	48	0	7	0.0% (0.0-6.1%)
	Unspecified		25	2	12	
	All		1,157	42	56	

Filter complications and device (n=1,171)



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Filter complication detail

The commonest filter complications consist of filter migration and caval wall perforation, which may have no clinical consequences. One filter (Celect) deployed in a supra-renal location, migrated to the intra-hepatic IVC, close to the right atrium and was retrieved. No catastrophic migrations to the heart or pulmonary arteries were recorded.

It is likely that asymptomatic perforation of the caval wall occurs with several filter types, and, in the absence of a CT scan will not be detected. Perforation was more commonly reported with the Bard Recovery and G2 filters than with other devices. Perforation was the reason for failure to retrieve the filter in 5 cases. Stent struts that penetrate the caval wall may occasionally cause symptoms due to penetration of adjacent organs. In one case, a filter leg was noted to be located within the aortic wall. It was retrieved without adverse consequences. No instances of symptomatic penetration of adjacent organs were recorded in the registry. No perforations were seen with the Cordis filters.

No major structural failures were reported. No filter complications were reported with any of the permanent devices. The filter complications described as *other* (18 patients) comprised 6 cases of IVC thrombosis, 7 of DVT, 3 possible puncture site complications and 11 apparently unrelated complications.

Filter device and filter complications detail

			Filter complications detail						
			None	Migration	Perforation	Structural	Other	Unspecified	All
Device	Retrievable	B Braun Tempofilter	1	0	0	0	0	0	1
		Bard G2	75	3	13	0	5	3	93
		Bard Recovery	44	1	5	0	0	1	50
		Cook Celect	281	1	1	0	3	10	295
		Cook Gunther Tulip	451	0	8	0	4	15	476
		Cordis OptEase	155	1	0	0	4	6	166
	Permanent	Pyramed ALN	8	0	0	0	1	0	9
		B Braun VenaTech LGM	2	0	0	0	0	0	2
		Cook Birds Nest	2	0	0	0	0	0	2
		Cordis TrapEase	65	0	0	0	0	2	67
		Simon Nitinol	48	0	0	0	0	7	55
	Unspecified		25	0	1	0	1	12	39
	All		1,157	6	28	0	18	56	1,255

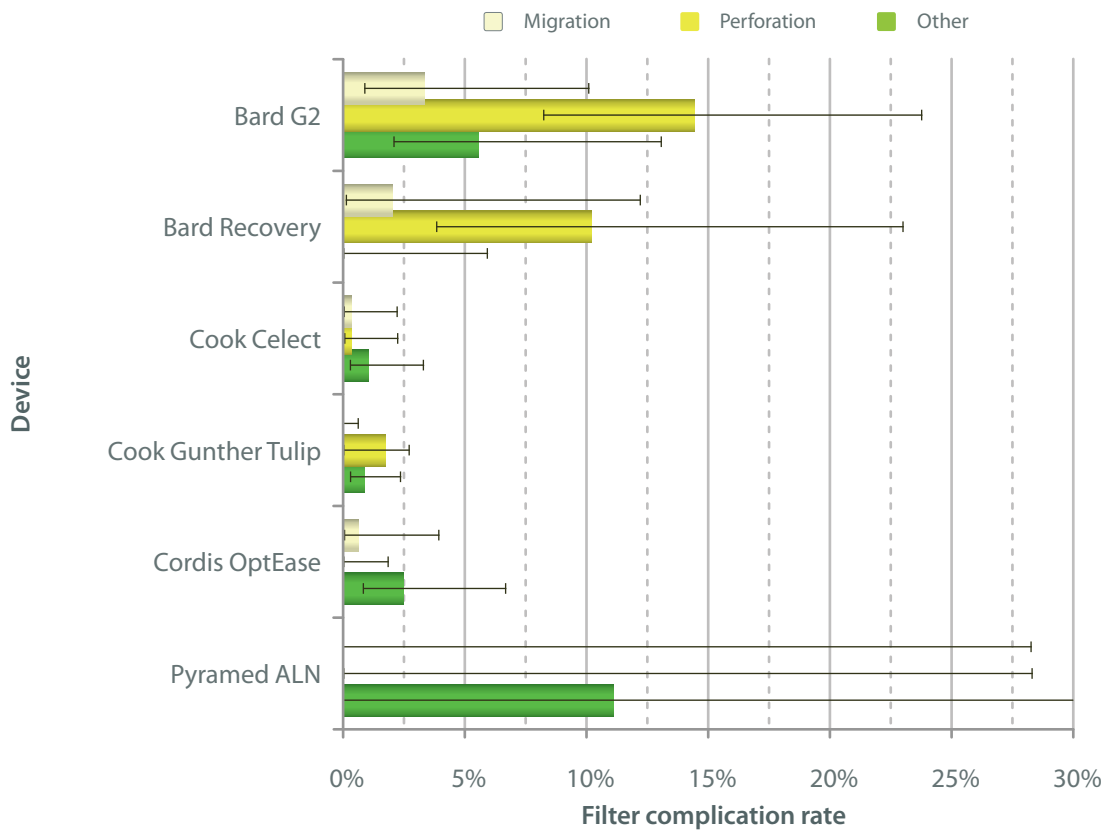
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Devices with reported filter complications:
details of filter complications (n=1,054)



Disclaimer

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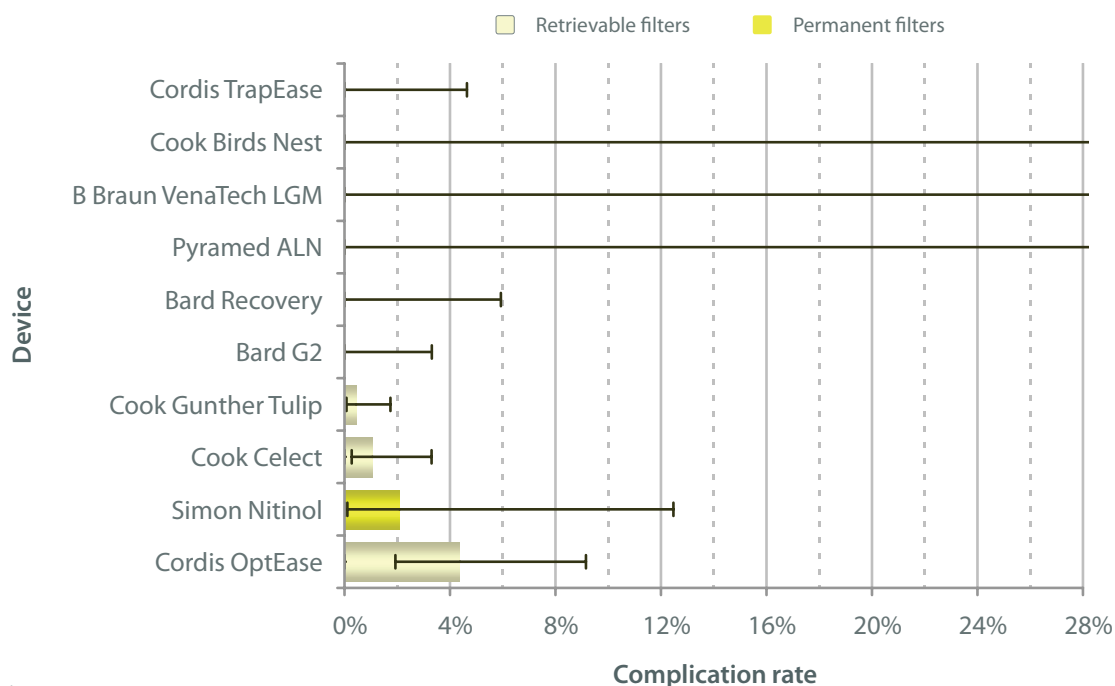
Post-filter placement DVT

DVT is a known risk of IVC filter placement. The rate identified in this series is low, which may reflect under-reporting of this complication. There are differences between the post-procedure rates of DVT for Cook Celect *versus* Cordis OptEase (2-sided Fisher's exact test; $p=0.004$) and for Cook Gunther Tulip *versus* Cordis OptEase (2-sided Fisher's exact test; $p=0.002$), but a funnel plot analysis using 99.9% control limits does not identify any significant outliers.

Filter device and post-filter placement DVT

			Post-filter placement DVT			
			No	Yes	Unspecified	Rate & 95% CI
Device	Retrievable	B Braun Tempofilter	0	1	0	100.0% (5.0-100.0%)
		Bard G2	89	0	4	0.0% (0.0-3.3%)
		Bard Recovery	49	0	1	0.0% (0.0-5.9%)
		Cook Celect	282	3	10	1.1% (0.3-3.3%)
		Cook Gunther Tulip	457	2	17	0.4% (0.1-1.7%)
		Cordis OptEase	153	7	6	4.4% (1.9-9.2%)
		Pyramed ALN	9	0	0	0.0% (0.0-28.3%)
	Permanent	B Braun VenaTech LGM	2	0	0	0.0% (0.0-77.6%)
		Cook Birds Nest	2	0	0	0.0% (0.0-77.6%)
		Cordis TrapEase	63	0	4	0.0% (0.0-4.6%)
		Simon Nitinol	47	1	7	2.1% (0.1-12.5%)
		Unspecified	27	0	12	
	All	1,180	14	61		

Post-filter placement DVT and device (n=1,166)



Disclaimer

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BSIR Inferior Vena Cava Filter Registry First IVC Filter Registry Report 2011

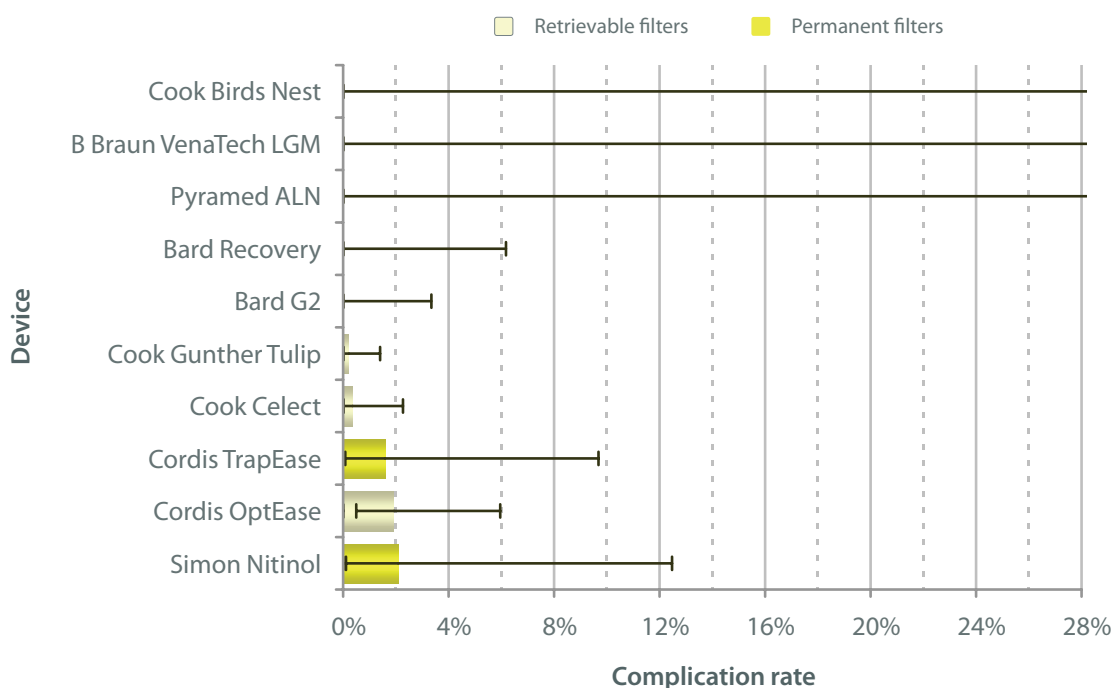
Post-filter placement PE

PE appears to be a rare event following IVC filter placement; however, the possibility of under-reporting should be borne in mind.

Filter device and post-filter placement PE

			Post-filter placement PE			
			No	Yes	Unspecified	Rate & 95% CI
Device	Retrievable	B Braun Tempofilter	0	0	1	Not applicable
		Bard G2	88	0	5	0.0% (0.0-3.3%)
		Bard Recovery	47	0	3	0.0% (0.0-6.2%)
		Cook Celest	281	1	13	0.4% (0.0-2.3%)
		Cook Gunther Tulip	458	1	17	0.2% (0.0-1.4%)
		Cordis OptEase	153	3	10	1.9% (0.5-6.0%)
		Pyramed ALN	9	0	0	0.0% (0.0-28.3%)
	Permanent	B Braun VenaTech LGM	2	0	0	0.0% (0.0-77.6%)
		Cook Birds Nest	2	0	0	0.0% (0.0-77.6%)
		Cordis TrapEase	62	1	4	1.6% (0.1-9.7%)
		Simon Nitinol	47	1	7	2.1% (0.1-12.5%)
	Unspecified		27	0	12	
	All		1,176	7	72	

Post-filter placement PE and device (n=1,156)



Disclaimer

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Other complications

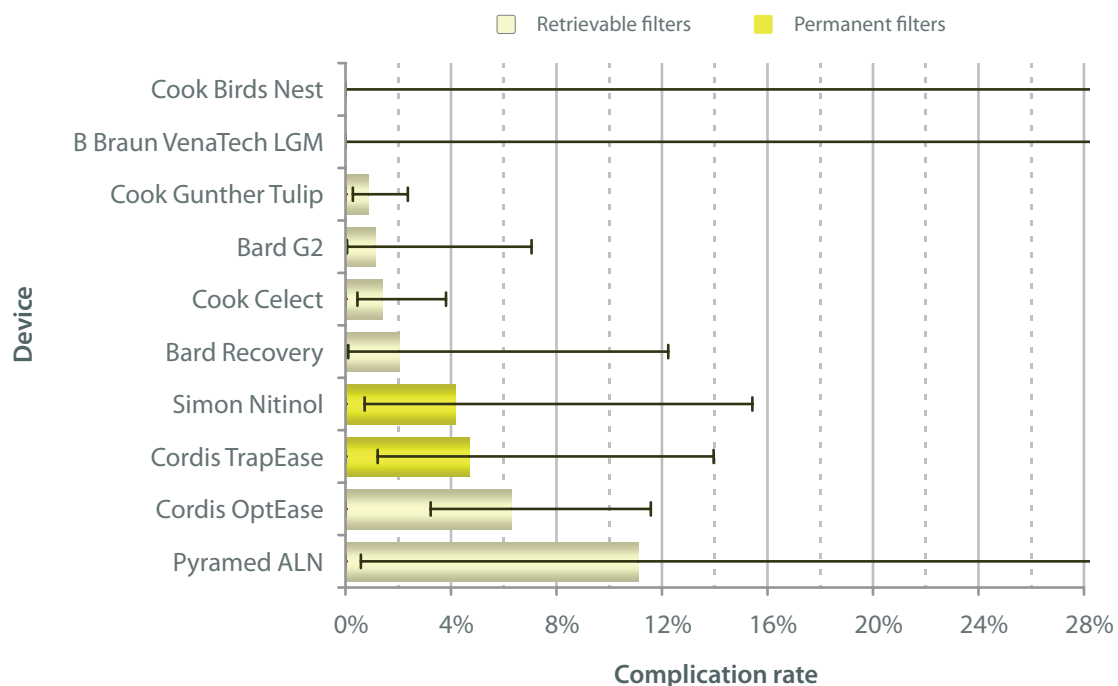
The reported incidence of DVT is significantly higher with the Cordis OptEase device than with the Cook Celest or Tulip, but a funnel plot analysis using 99.9% control limits does not identify any significant outliers.

According to the free text box used to qualify details on complications, some of these other complications were related to DVT and IVC thrombosis. Others were apparently unrelated to the IVC filter.

Filter device and other complications

			Other complications			
			No	Yes	Unspecified	Rate & 95% CI
Device	Retrievable	B Braun Tempofilter	0	1	0	100.0% (5.0-100.0%)
		Bard G2	87	1	5	1.1% (0.1-7.1%)
		Bard Recovery	48	1	1	2.0% (0.1-12.2%)
		Cook Celest	280	4	11	1.4% (0.5-3.8%)
		Cook Gunther Tulip	457	4	15	0.9% (0.3-2.4%)
		Cordis OptEase	149	10	7	6.3% (3.2-11.6%)
		Pyramed ALN	8	1	0	11.1% (0.6-49.3%)
	Permanent	B Braun VenaTech LGM	2	0	0	0.0% (0.0-77.6%)
		Cook Birds Nest	2	0	0	0.0% (0.0-77.6%)
		Cordis TrapEase	61	3	3	4.7% (1.2-14.0%)
		Simon Nitinol	46	2	7	4.2% (0.7-15.4%)
	Unspecified		26	1	12	
	All		1,166	28	61	

Other complications and device (n=1,166)



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Retrieval



Retrieval

Retrieval attempted

Of 621 filters placed with the intention of retrieval, there is no retrieval information on 167. We do not know whether or not these filters were removed as intended. It is probable that some filters were placed with the intention of retrieval, but the patients were not referred back to the radiology department for this procedure and the filters were unintentionally left in place permanently. We believe that radiologists must take responsibility for arranging the retrieval of temporary filters.

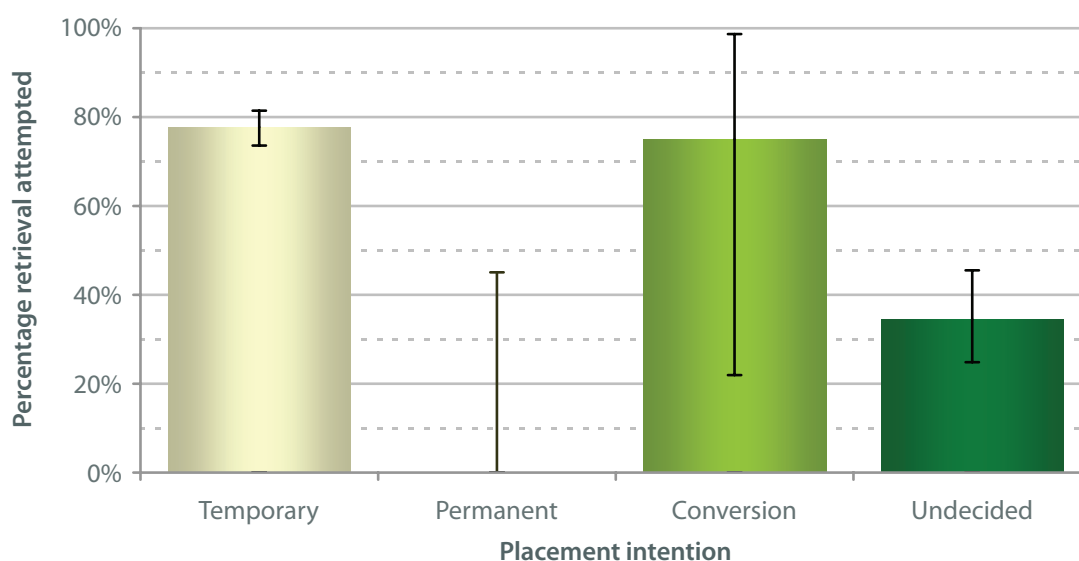
Where follow-up information is available, retrieval was attempted for 77.8% of filters intended for temporary placement. The reasons for not retrieving the remaining 22.2% included clinical deterioration and caval thrombosis. Follow-up data indicate that this group has poor long-term survival reflecting the clinical deterioration (see page 77). For the filters where there was no initial decision on the intended duration of filter placement, 34.5% were retrieved.

Retrieval seems to be a straightforward procedure, with 67.9% taking less than 30 minutes. There were no statistically significant differences in retrieval times for the various devices recorded in the Registry.

Retrieval and placement intention

		Attempt to retrieve filter				
		No	Yes	Unspecified	All	Proportion attempted
Placement intention	Temporary	101	353	167	621	77.8%
	Permanent	5	0	475	480	0.0%
	Conversion	1	3	0	4	75.0%
	Undecided	57	30	52	139	34.5%
	Unspecified	0	1	10	11	100.0%
	All	164	387	704	1,255	70.2%

Attempted retrieval and placement intention (n=550)



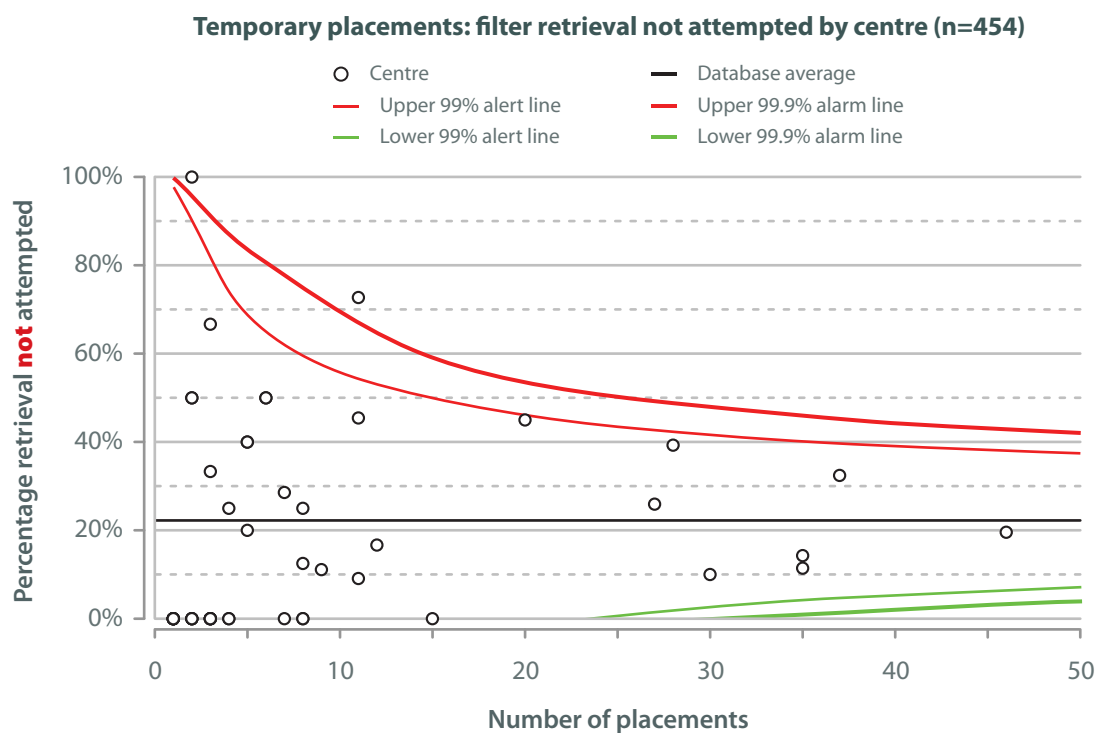


Retrieval of temporary placements by centre

There is almost certainly a subset of patients in whom retrieval was intended, but was not undertaken because the patient was lost to follow up. We believe that it is important that the Radiologist who places a filter with the intention of retrieving it takes responsibility for ensuring that the patient is re-called for retrieval at a suitable interval. This is probably most easily achieved by prospectively arranging for patients to return for their retrieval procedure on the local hospital Radiology Management Systems (RMS).

The funnel plot below shows substantial variation in rate of attempted retrieval between centres and a single centre above the upper alarm line with no attempted retrieval in 75% of those for whom temporary placement was planned.

In some patients retrieval is contraindicated by the presence of caval thrombus.





Retrieval success

In the majority of cases, 82.3%, retrieval is successful; but, in a significant minority, 17.7%, retrieval fails. However, of greater concern is the fact that in the 25 pregnant women reported in the Registry, there was no recorded attempt at retrieval in 2 patients, failure to retrieve in 6 and successful retrieval was recorded in only 12 patients; the retrieval data were missing for the other 5 entries.

Attempted retrievals: successful retrieval

		Data	
		Count	Rate & 95% CI
Retrieval success	No	68	17.7% (14.1-22.0%)
	Yes	316	82.3% (78.0-85.9%)
	Unspecified	2	
	All	386	

Duration of implant and make of device

Looking at duration of placement for each the various filter models recorded in the registry where retrieval was attempted, there are clear difference in dwell times:

- Bard G2 median dwell time 77.5 days (n=40)
- Bard Recovery 77 days (n=15)
- Cook Celest 32 days (n=123)
- Cook Gunther Tulip 39.5 days (n=132)
- Cordis OptEase 12 days (n=45)

The duration of placement is significantly shorter for the Cordis OptEase filter compared to any of the other filters ($p < 0.001$).

Disclaimer

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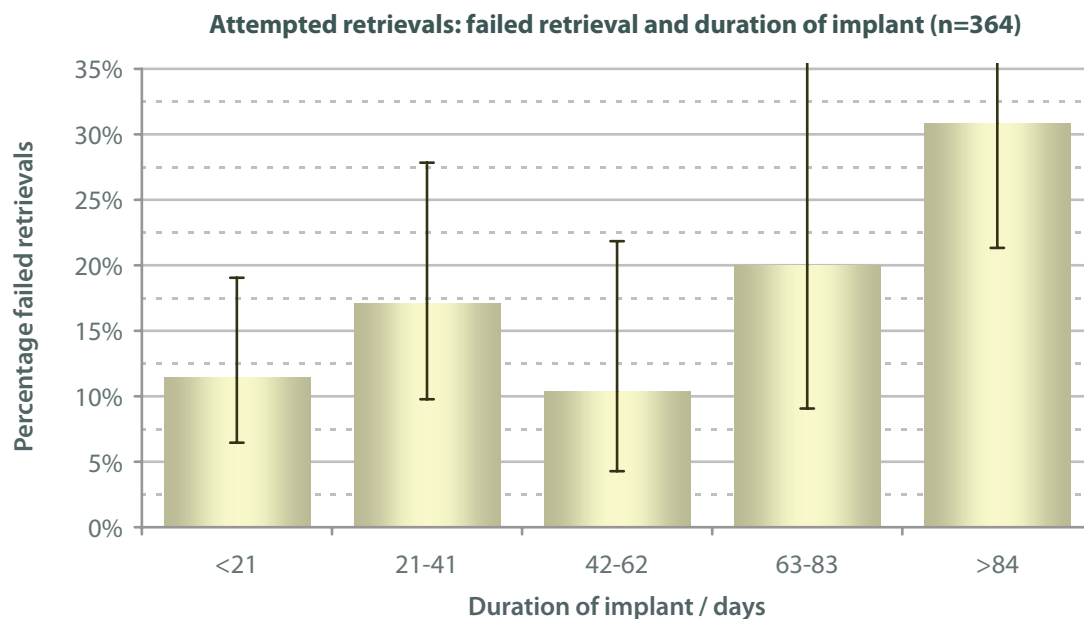


Retrieval success and duration of implant

Retrieval success diminishes with duration of implantation. Filters that have been deployed for more than 9 weeks (>62 days) are significantly less likely to be successfully retrieved as compared with those with a shorter duration of implantation (2x2 contingency table; $p=0.001$). This is most likely to be because of incorporation of the device in the caval wall, sometimes due to IVC thrombosis, and penetration of the caval wall by the filter legs.

Attempted retrievals: successful retrieval and duration of implant

		Successful retrieval				Proportion failed
		No	Yes	Unspecified	All	
Duration of implant	<21 days	13	101	0	114	11.4%
	21-41 days	13	63	2	78	17.1%
	42-62 days	6	52	0	57	10.3%
	63-83 days	7	28	0	35	20.0%
	>83 days	25	56	0	81	30.9%
	Unspecified	4	16	0	20	20.0%
	All	68	316	0	386	17.7%





Retrieval success and device

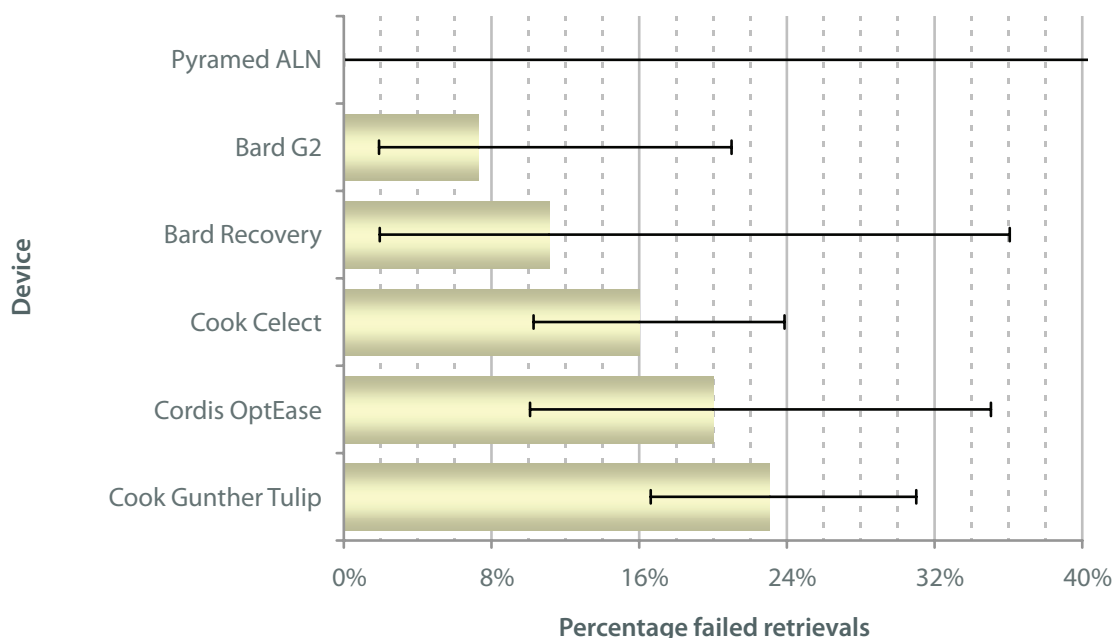
The mechanism of filter retrieval varies between manufacturers. The Bard devices rely on trapping the apex of the filter in a cone. The Cook and Cordis filters require snaring of a small hook located on the apex (Cook) or base (Cordis) of the filter. Snaring the hook is difficult if the filter is tilted or the hook is embedded in the caval wall. Non-standard retrieval techniques using intra-arterial forceps, balloons to displace the apex or wire loops passed through the filter were employed in isolated cases when the apex could not be snared.

With the exception of ALN, for which numbers are very small, the Bard filters combined had the highest rate of retrieval success, despite having the longest in-dwell times, but individually this did not reach statistical significance.

Attempted retrievals: successful retrieval and device

		Successful retrieval			
		No	Yes	Unspecified	Failure rate & 95% CI
Device	Bard G2	3	38	0	7.3% (1.9-21.0%)
	Bard Recovery	2	16	0	11.1% (1.9-36.1%)
	Cook Celect	20	105	1	16.0% (10.3-23.9%)
	Cook Gunther Tulip	33	110	1	23.1% (16.6-31.0%)
	Cordis OptEase	9	36	0	20.0% (10.1-35.1%)
	Pyramed ALN	0	3	0	0.0% (0.0-63.2%)
	Unspecified	1	8	0	
	All	68	316	2	

Attempted retrievals: failed retrieval and device (n=375)



Disclaimer

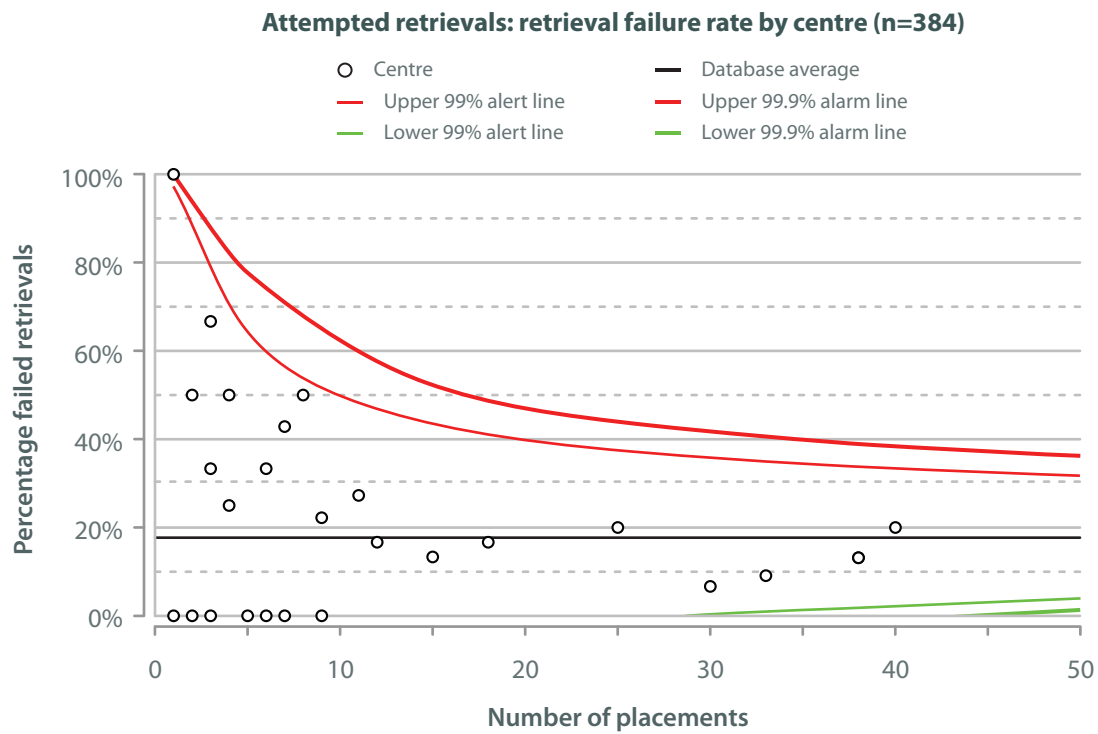
Analyses of the type of device are not intended to be representative of market share as the registry is not currently capturing all procedures performed in the United Kingdom.



Retrieval success and centre

The funnel plot indicates all centres and all operators fall within the 99% control limits, indicating that there were no significant outliers.

There seems to be the suggestion of a relationship between the rate of successful retrieval and the number of retrievals attempted. High-volume centres tend to achieve a better than average success rate.



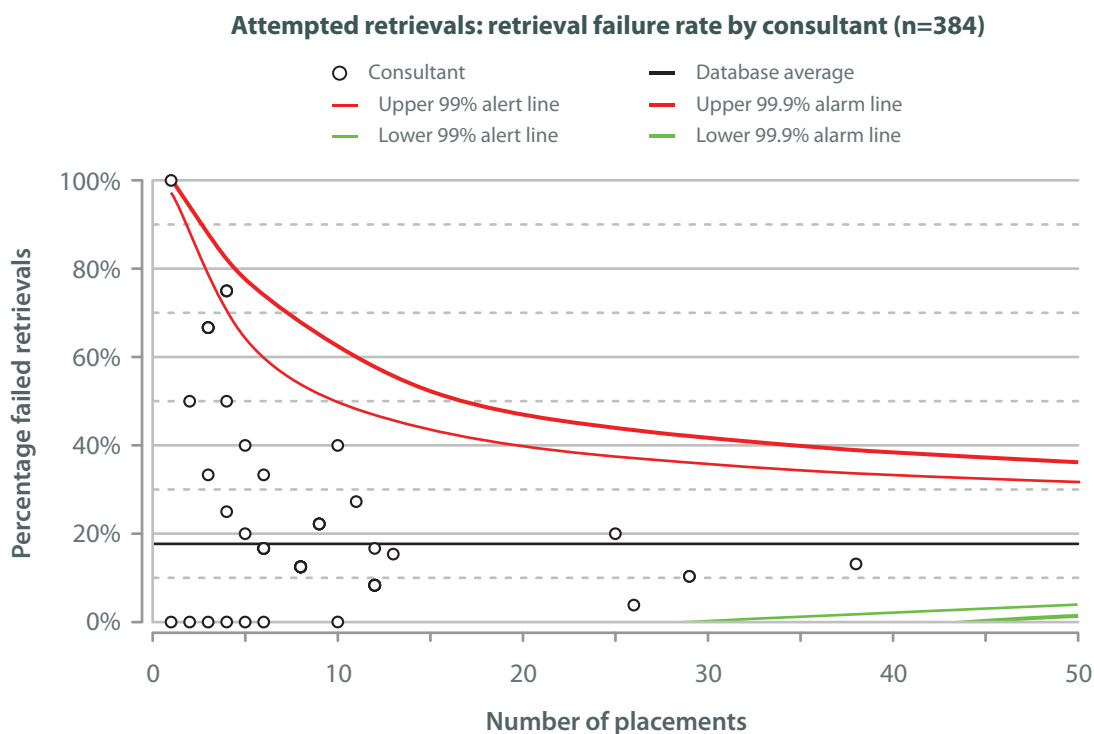


Retrieval success and consultant

The rates of retrieval success for the vast majority of consultants fall well within the 99% alert lines, confirming good technical skills for filter retrieval by operators in the United Kingdom.

Funnel plots enable individuals to establish whether or not their results are in line with national data, even when only a relatively small number of procedures are performed. When an individual's data point approaches or crosses the alert line, appropriate and timely action, such as further training, can be initiated.

Retrieval





Retrieval success and orientation

Although one would expect centralised filters to be associated with a higher rate of successful retrieval, this effect has not reached statistical significance in the Registry.

Contrary to expectation, retrieval success of the Cook Celect and Tulip filters was unrelated to filter tilting, with success rates of around 80% for all orientations. It may be that tilting was not recognised at the time of deployment, or possibly that it occurred at a later date. For the other filters in this registry, tilting was associated with a lower success rate of filter retrieval ($p=0.004$).

Attempted retrievals: successful retrieval and filter orientation

		Successful retrieval				
		No	Yes	Unspecified	All	Proportion failed
Orientation	Centralised	45	231	1	277	16.3%
	Tilted	12	35	1	48	25.5%
	Apex abutting caval wall	5	10	0	15	33.3%
	Unspecified	6	40	0	46	13.0%
	All	68	316	2	386	17.7%

Attempted retrievals: retrieval success rate and device

		Orientation		
		Centralised	Tilted	Apex abutting caval wall
Device	Bard G2	97.1% (n=35)	75.0% (n=4)	0.0% (n=1)
	Bard Recovery	100.0% (n=15)	50.0% (n=2)	0.0% (n=0)
	Cook Celect	81.9% (n=94)	88.9% (n=18)	85.7% (n=7)
	Cook Gunther Tulip	79.8% (n=99)	65.0% (n=20)	66.7% (n=6)
	Cordis OptEase	73.9% (n=23)	50.0% (n=2)	0.0% (n=1)
	Pyramed ALN	100.0% (n=3)	0.0% (n=0)	0.0% (n=0)
	Unspecified	85.7% (n=7)	100.0% (n=1)	0.0% (n=0)
	All	83.7% (n=276)	74.5% (n=47)	66.7% (n=15)



Retrieval complications

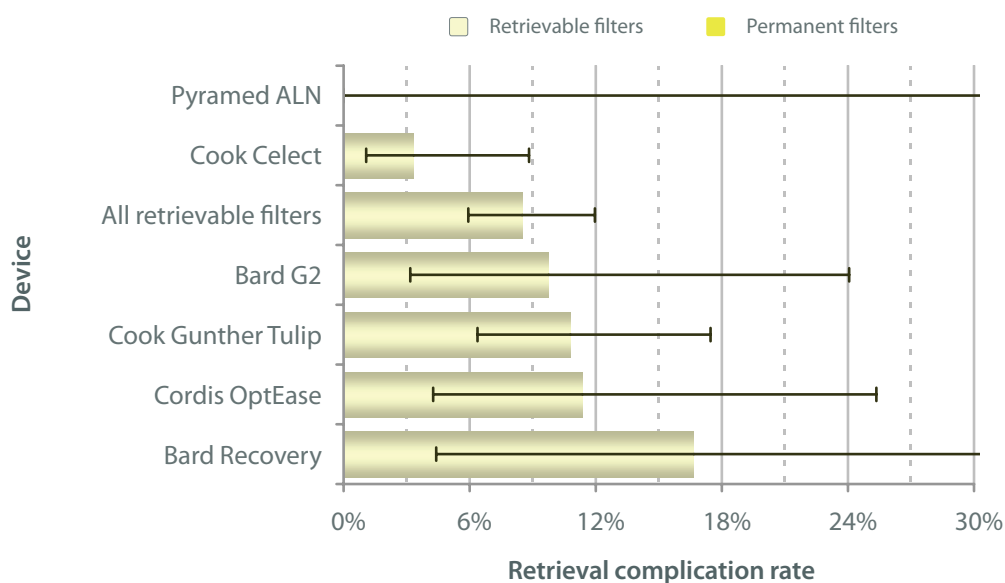
Retrieval complications and device

Reported complication rates are in the range 0.0-16.7% on a device by device basis; on review of the detailed description data on the recorded filter complications, it transpires that the majority of these were not true retrieval complications. There were three caval tears reported, which were not associated with adverse clinical consequences, and one dissection of the internal jugular vein. There were three mechanical or structural failures of the retrieval device of the Cook Gunther Tulip filter with no significant clinical *sequelae*, and retrieval was successfully achieved using a modified technique. The majority of the other reported complications were due to tilting of the filter, strut perforation or thrombosis, which made retrieval difficult or impossible.

Attempted retrievals: retrieval complications for each make of device

		Retrieval complications			
		No	Yes	Unspecified	Complication rate
Device	Bard G2	37	4	0	9.8%
	Bard Recovery	15	3	0	16.7%
	Cook Celect	116	4	6	3.3%
	Cook Gunther Tulip	124	15	5	10.8%
	Cordis OptEase	39	5	1	11.4%
	Pyramed ALN	3	0	0	0.0%
	Unspecified	6	2	1	
	All	340	33	13	

Attempted retrievals: retrieval complications & device (n=365)



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Retrieval complications and duration of insertion

The recorded follow up data indicate that retrieval complication rates approximately double once the dwell time exceeds 9 weeks, although there was no statistically significant relationship between dwell time and retrieval complication rates.

Filters intended for temporary placement where retrieval was attempted: retrieval complications and duration of insertion

		Retrieval complications			
		No	Yes	Unspecified	Complication rate
Duration of insertion	<21 days	96	7	3	6.8%
	21-41 days	64	5	5	7.2%
	42-62 days	49	4	1	7.5%
	63-83 days	28	2	1	6.7%
	>83 days	59	10	2	14.5%
	Unspecified	13	3	1	
	All	309	31	13	





**Long-term
outcomes**

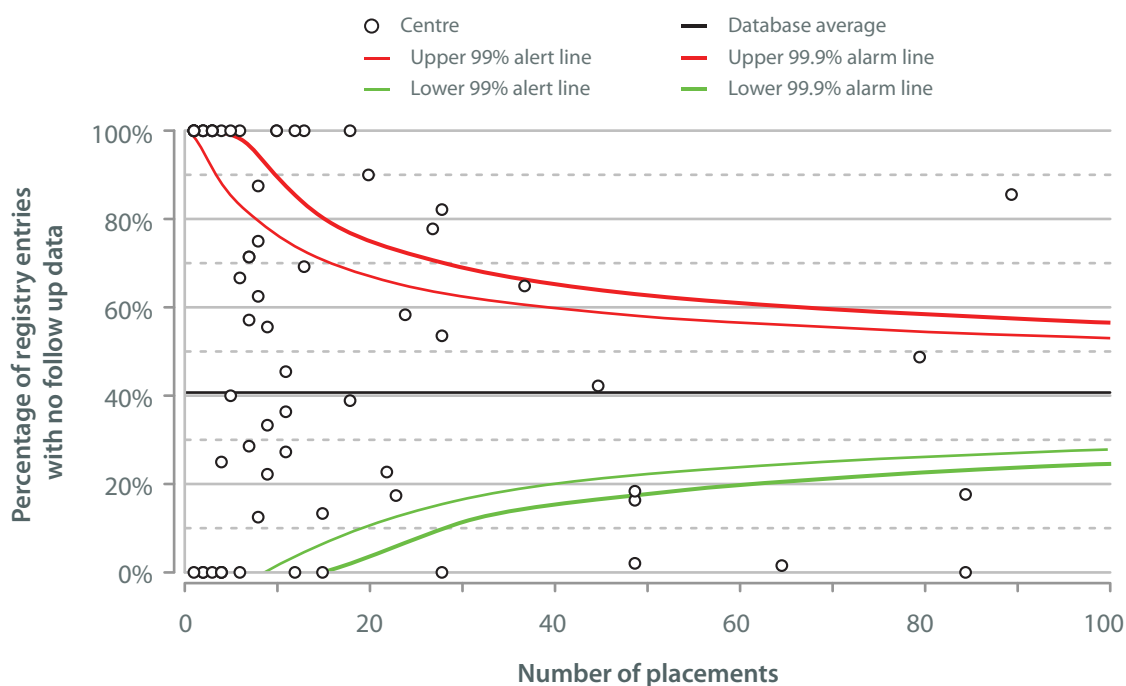


Long-term outcomes

Entry of follow up data

One-year follow up data was considered to be a very important aspect of this registry, and registrants were encouraged to complete the follow up forms by regular email reminders. Despite this, one year follow-up data is missing in a substantial minority of registered cases. 40.7% (476 / 1,169) of patients who were discharged alive from hospital following filter placement had no follow up recorded.

Completeness of follow up data by centre excluding patients reported as deceased immediately following the procedure (n=1,169)





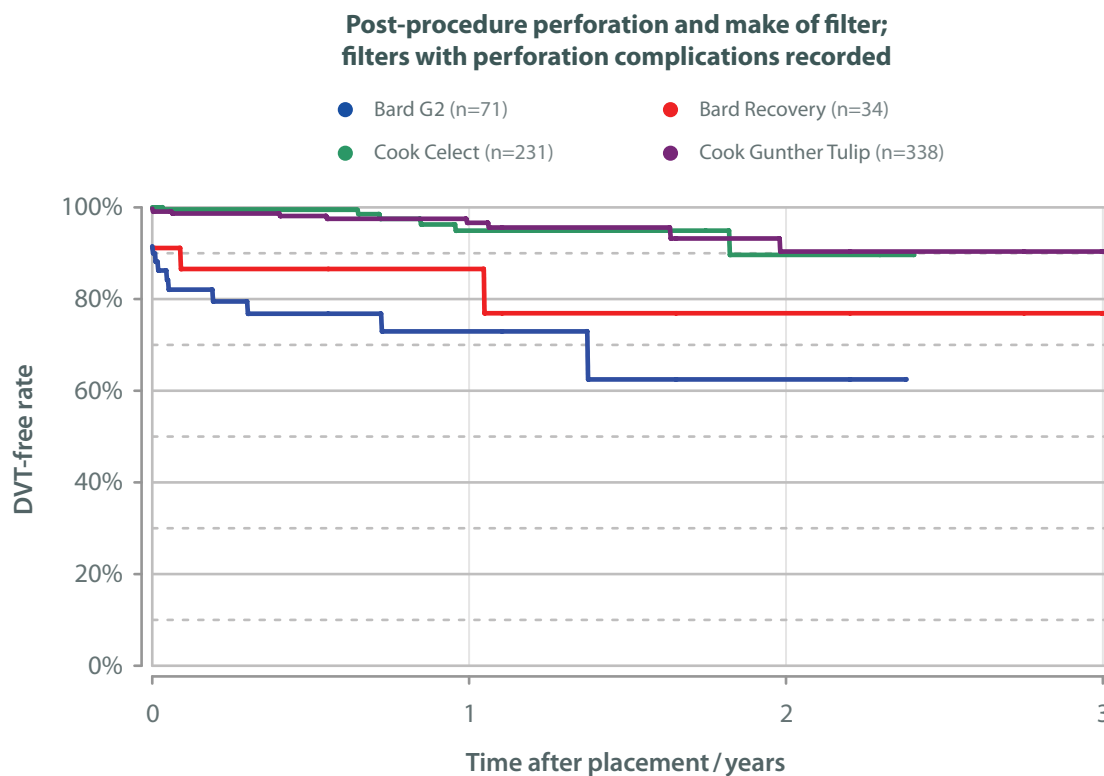
Filter complications

Migration

A total of 9 migrations have been reported: 4 with Bard G2 filter, 3 with the Cook Celect filter, and 1 each with the Bard Recovery and Cordis OptEase filters. Contributors were asked to report migrations of >10 mm. This total includes the 6 previously reported as *Post-procedure* complications on page 49. Migrations were noted in both cranial and caudal directions. There were no catastrophic migrations to the heart or pulmonary arteries.

Perforation

No perforations of the caval wall were noted with the Cordis devices. Perforation was more frequently reported with the Bard Recovery and G2 devices.





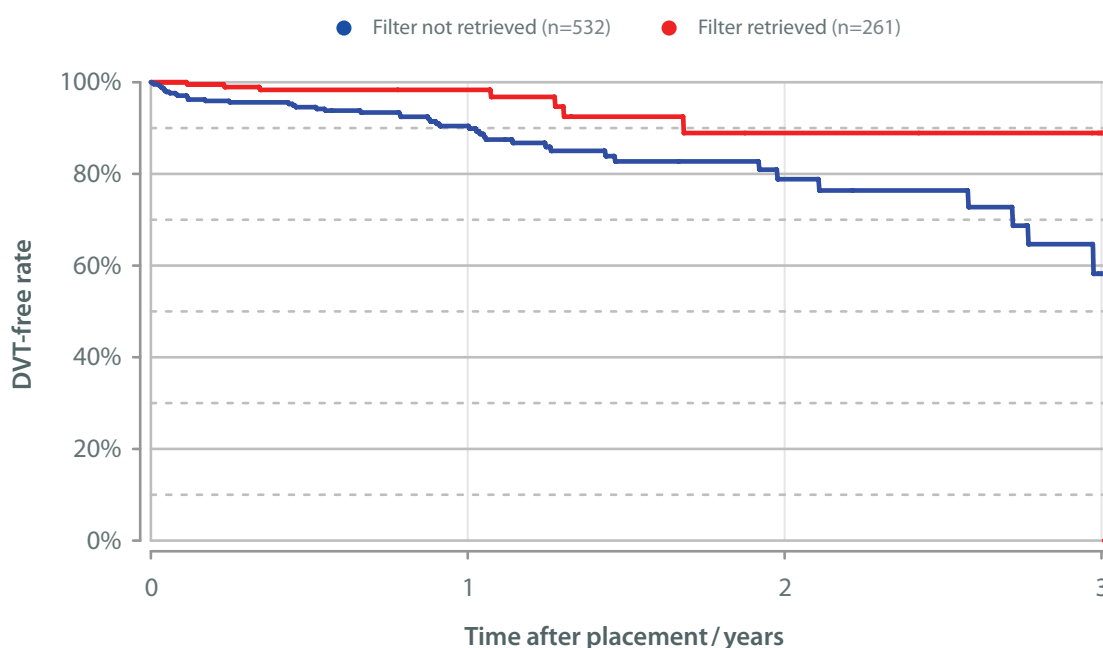
Deep vein thrombosis

DVT and filter retrieval

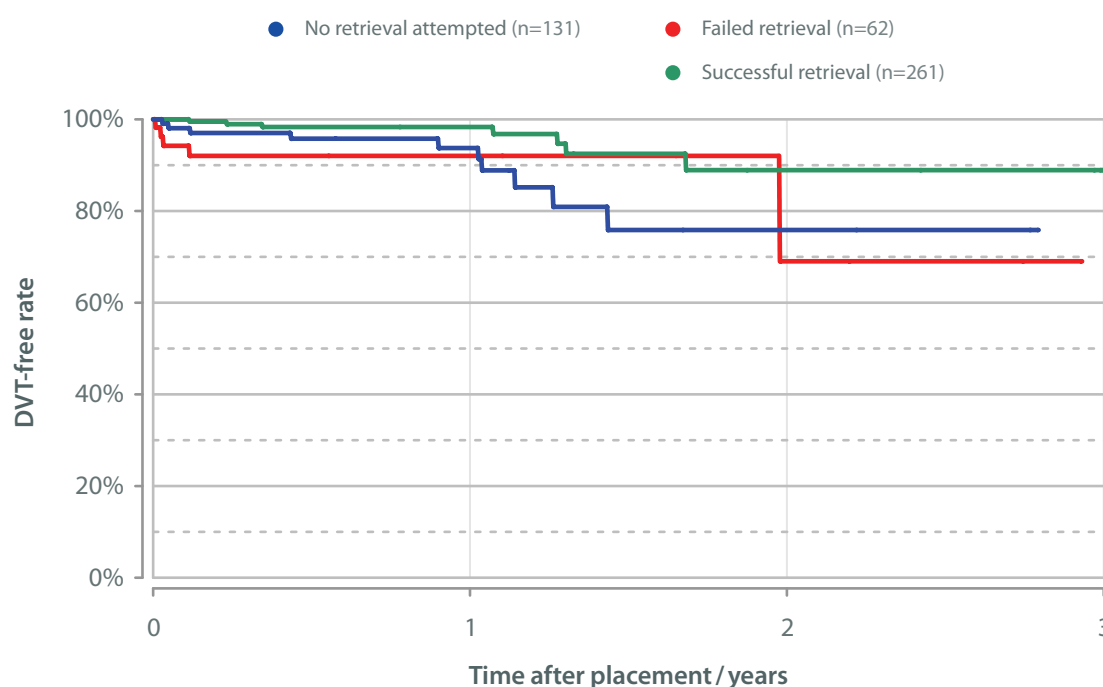
Recurrent DVT is a known risk factor following caval filter placement. The proportion of these that can be attributed to the presence of the filter is speculative. A large thrombus in the filter might indicate successful trapping of a potentially fatal thrombus, and could therefore be an indication that the filter has been effective. Alternatively, the filter itself may be a *nidus* for thrombus formation. Indeed, in some cases, thrombus was identified on the cranial side of the filter. There was no statistically significant difference in DVT rates found in this registry between those patients who had successful filter retrieval compared to those that had their filters left in place.

Long-term outcomes

DVT reported during follow up and filter retrieval



Non-permanent filter placements: post-procedure DVT and retrieval

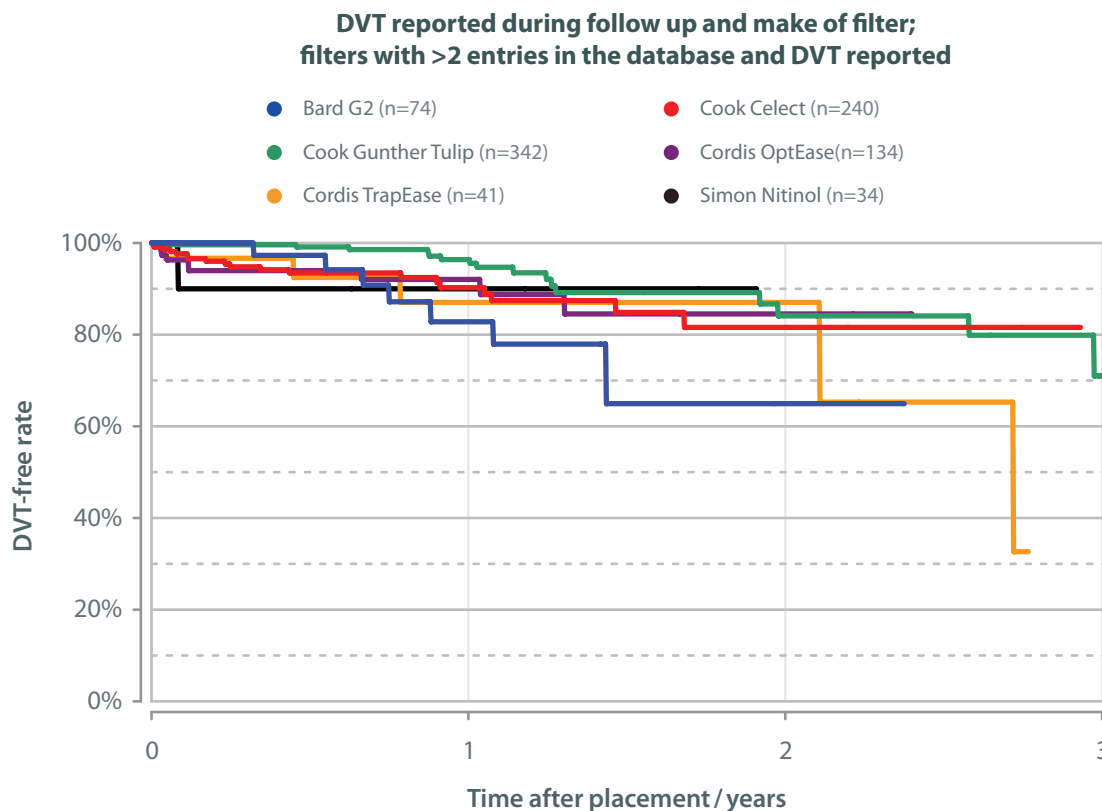




DVT and device

Following the PREPIC study, there is a known increased risk of DVT following the placement of IVC filters. This is probably due to local trauma at the insertion site and / or change in flow dynamics in the IVC following filter placement.

Although immediate outcomes following filter placement showed some differences in DVT rates between devices (see page 51), there were no statistically significant differences in the incidence of DVT between devices over the 3 years of follow up presented in the chart below.



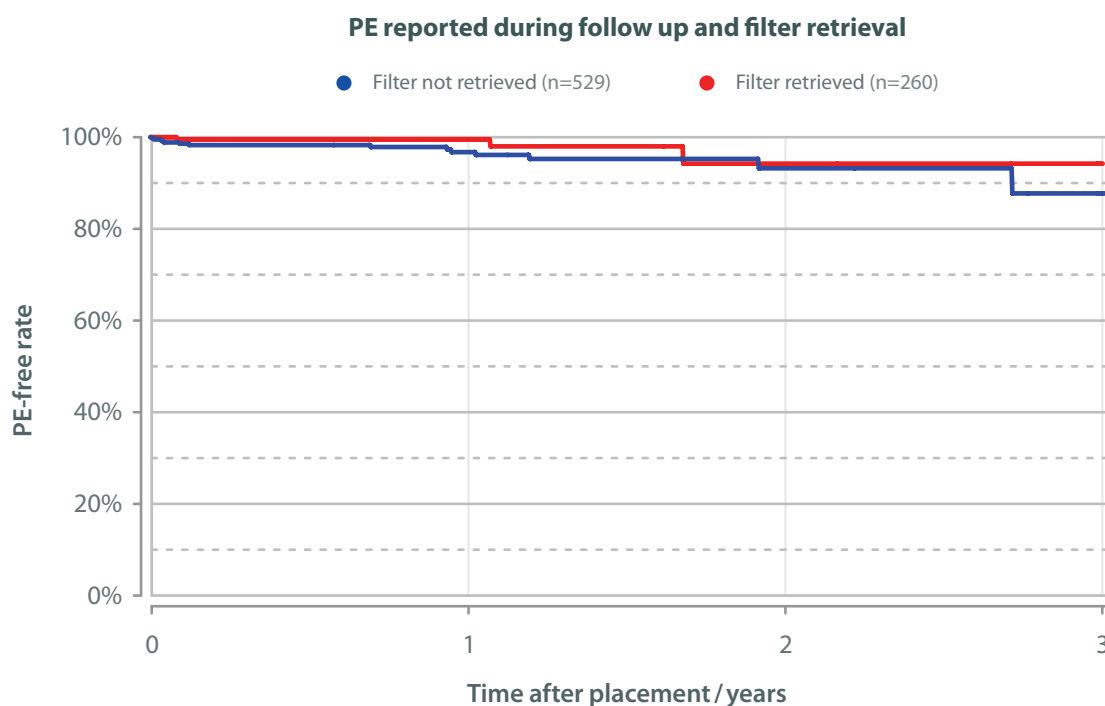


Pulmonary embolus

PE and filter retrieval

Operators may be concerned that, when a filter has been removed, the patient may be exposed to a higher risk of future pulmonary embolism than if the filter had been left *in situ*. According to the data reported to this registry, this does not appear to be the case: the risk of further pulmonary embolism is the same whether or not the filter is retrieved.

Long-term outcomes





Mortality

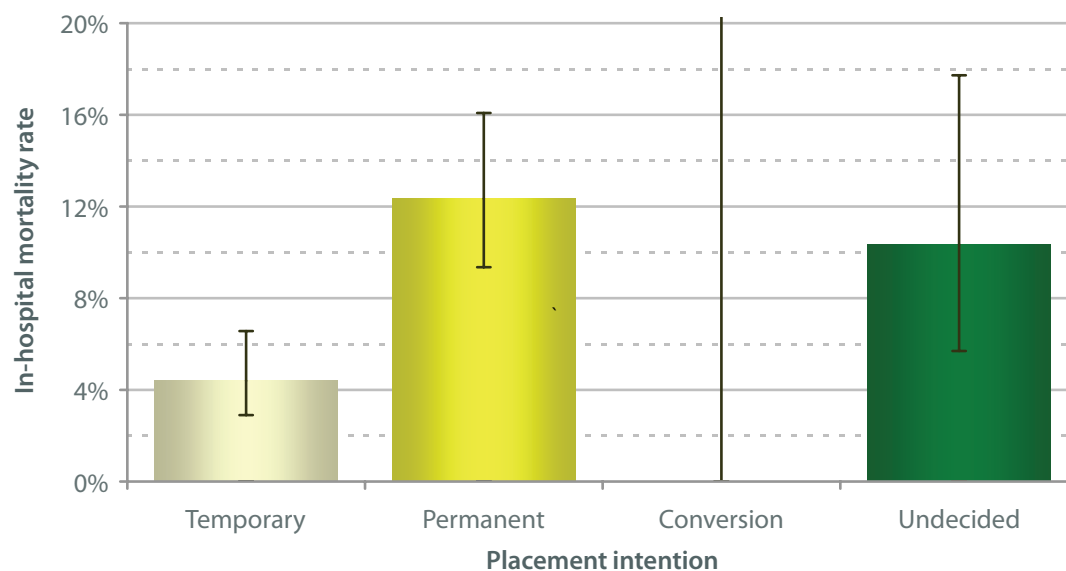
In-hospital mortality and placement intention

The average in-hospital mortality rate following IVC filter placement is 8.1% indicating that this patient population is overall a high risk group of individuals with most probably a more significant mortality risk from underlying existing conditions. The large group of patients who have permanent filters inserted appear to have an elevated mortality rate of 12.3% while, as expected, those patients with temporary filters (and most probably only a temporary risk of PE) have a lower mortality rate of 4.3%. The difference in mortality, both in-hospital and at 30 days, between temporary and permanent placements is probably due to difference in severity of the underlying disease.

In-hospital mortality and placement intention

		In-hospital mortality			
		Alive	Dead	Unspecified	Mortality rate & 95% CI
Placement intention	Temporary	522	24	75	4.4% (2.9-6.6%)
	Permanent	348	49	83	12.3% (9.4-16.1%)
	Conversion	4	0	0	0.0% (0.0-52.7%)
	Undecided	104	12	23	10.3% (5.7-17.7%)
	Unspecified	1	1	9	50.0% (2.7-97.3%)
	All	979	86	190	8.1% (6.5-9.9%)

In-hospital mortality and placement intention (n=1,063)





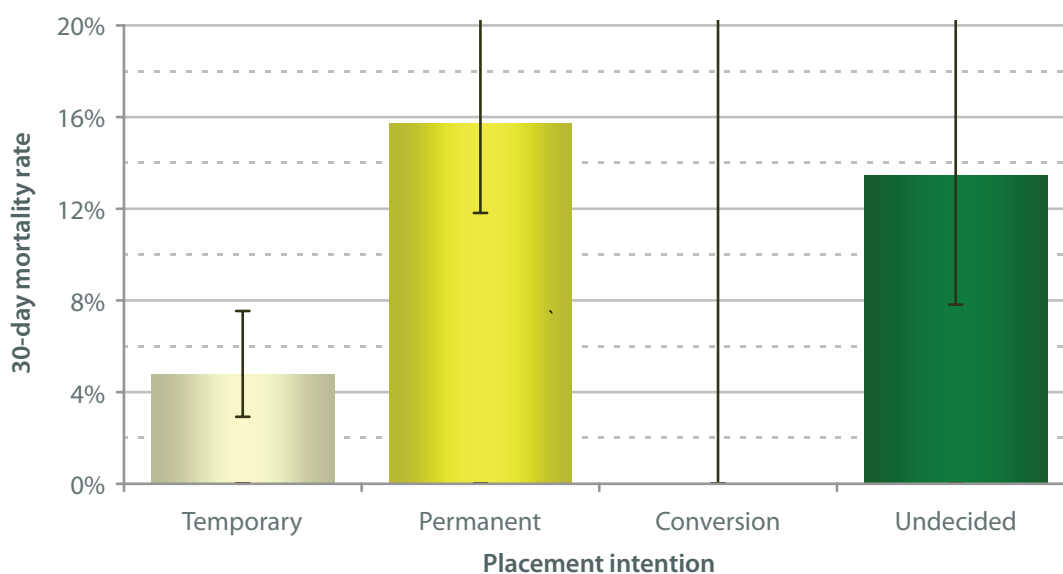
30-day mortality and placement intention

As discussed previously, the difference in mortality, both in-hospital and at 30 days, between temporary and permanent placement is due to difference in severity of the underlying disease.

30-day mortality and placement intention

		30-day mortality			
		Alive	Dead	Unspecified	Mortality rate & 95% CI
Placement intention	Temporary	361	18	242	4.7% (2.9-7.5%)
	Permanent	241	45	194	15.7% (11.8-20.6%)
	Conversion	1	0	3	0.0% (0.0-95.0%)
	Undecided	90	14	35	13.5% (7.8-21.9%)
	Unspecified	2	1	8	33.3% (1.8-87.5%)
	All	695	78	482	10.1% (8.1-12.5%)

30-day mortality and placement intention (n=770)



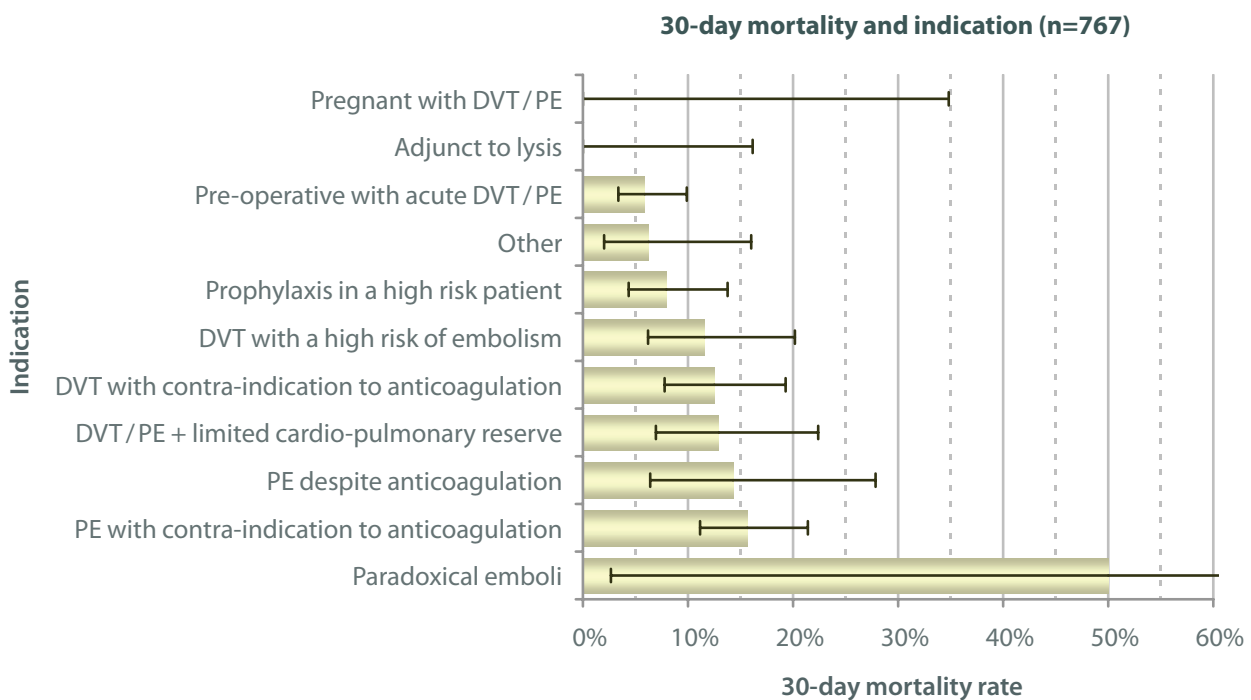


30-day mortality and indication

The 30-day mortality is a reflection of severity of the underlying disease. It is reassuring to note that no deaths were reported in the pregnant patients, although data is incomplete.

30-day mortality and indication

		30-day mortality			
		No	Yes	Unspecified	Rate (& 95% CI)
Indication	PE despite anticoagulation	74	11	52	12.9% (6.9-22.4%)
	PE with contra-indication to anticoagulation	178	33	107	15.6% (11.2-21.4%)
	DVT/PE plus limited cardio-pulmonary reserve	42	7	12	14.3% (6.4-27.9%)
	DVT with high risk of embolism	84	11	70	11.6% (6.2-20.2%)
	Paradoxical emboli	1	1	2	50.0% (2.7-97.3%)
	DVT with contra-indication to anticoagulation	126	18	84	12.5% (7.8-19.3%)
	Adjunct to lysis	7	0	7	0.0% (0.0-34.8%)
	Prophylaxis in a high risk patient	139	12	110	7.9% (4.4-13.8%)
	Pre-operative with acute DVT/PE	224	14	138	5.9% (3.4-9.9%)
	Pregnant with DVT/PE	17	0	8	0.0% (0.0-16.2%)
	Other	60	4	31	6.3% (2.0-16.0%)
	Unspecified	6	0	7	
	Patient denominator	695	78	482	





Long-term survival

Survival and placement intention

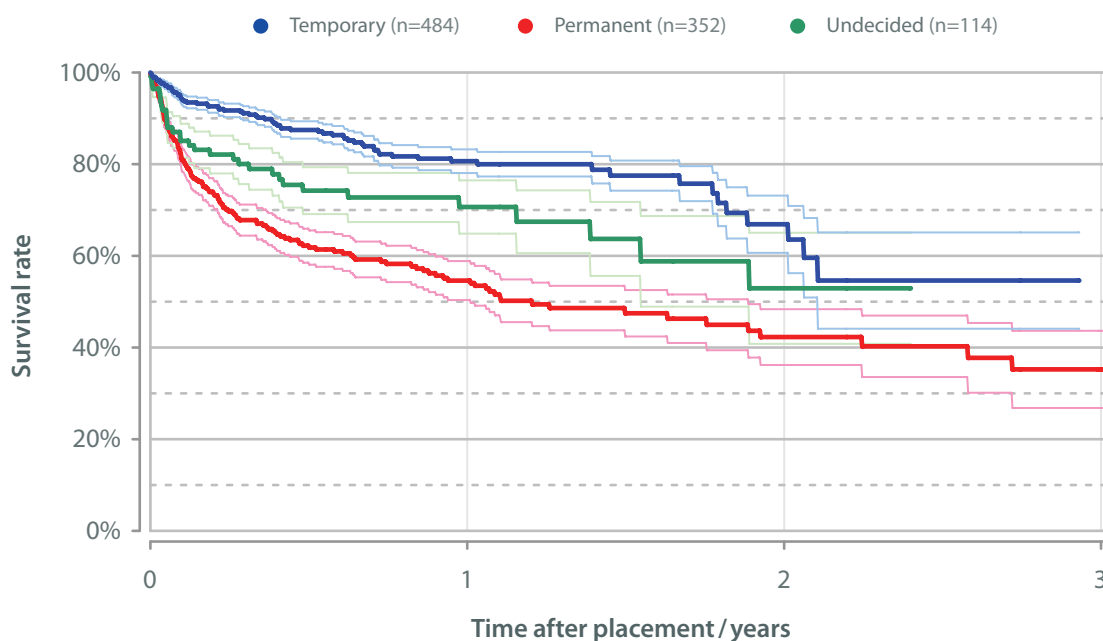
The long-term survival rates following IVC Filter placement are shown in the Kaplan-Meier survival curves below.

It is clear that the initial decision regarding temporary *versus* permanent filter placement is based on objective clinical criteria, which are reflected in the long-term mortality rates following placement. The temporary option is more likely to be selected for patients with a better chance of long-term survival (temporary *versus* permanent placements; $p < 0.001$; permanent *versus* undecided; $p = 0.016$; undecided *versus* temporary; $p = 0.009$).

There were 2 PE-related deaths in-hospital (of 86 deaths / 1,065 filter placements) and 3 during the follow up period; all but one were permanent placements. However, on closer enquiry, at least some of the data on these cases had been entered incorrectly and need to be treated with caution.

Notably, there were no filter-related deaths reported in this Registry.

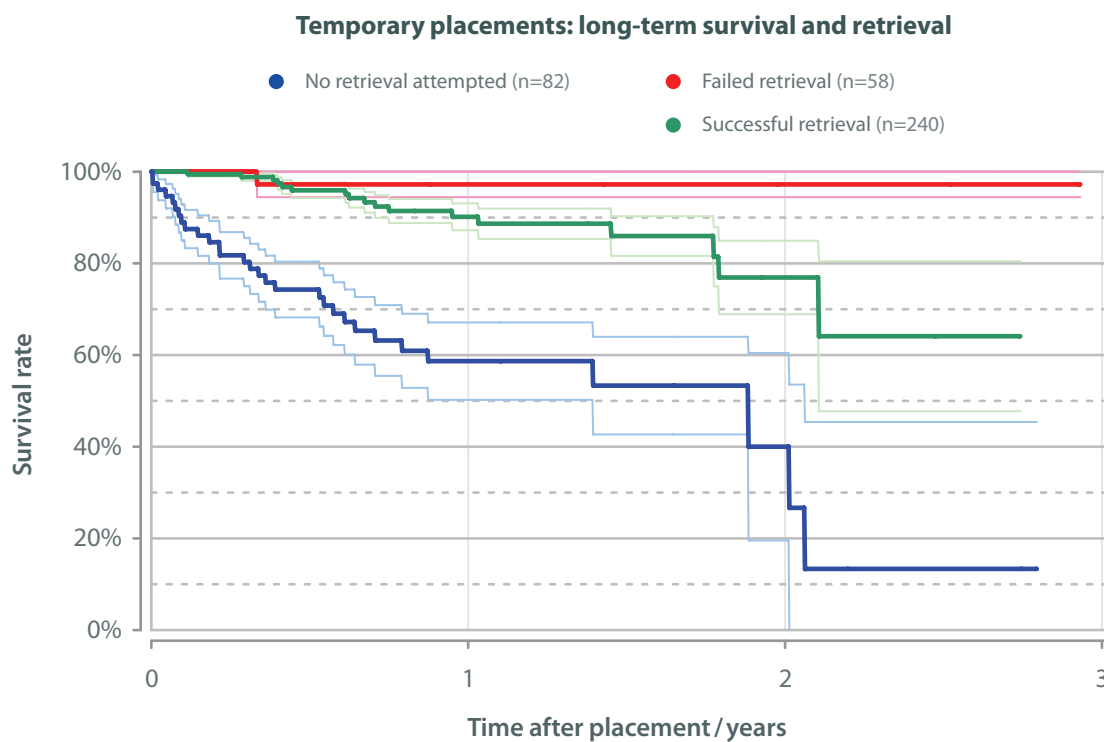
Long-term survival and placement intention





Survival and retrieval

The high mortality in the group where no retrieval was attempted is probably due to deterioration in the patient's underlying clinical condition. There was no significant difference in mortality between patients who had failed *versus* successful retrieval.







Appendices



Appendices

Taken from the quality improvement guidelines of the CIRSE



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Quality improvement guidelines for percutaneous inferior vena cava filter placement for the prevention of pulmonary embolism

Indications

1. Patients with evidence of pulmonary embolus or IVC, iliac, or femoral-popliteal DVT, and one or more of the following:
 - a. Contra-indication to anticoagulation
 - b. Complication of anti-coagulation
 - c. Failure of anti-coagulation
 - i. recurrent PE despite adequate therapy
 - ii. inability to achieve adequate anti-coagulation

Additional indications for selected patients

1. Massive pulmonary embolism with residual deep venous thrombus in a patient at high risk of further PE
2. Free floating iliofemoral or inferior vena cava thrombus
3. Severe cardiopulmonary disease and DVT (*e.g.*, cor pulmonare 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)

References

1. Decousus H, Leizorovicz A, Parent F, Page Y, Tardy B, Girard P, Laporte S, Faivre R, Charbonnier B, Barral FG, Huet Y, Simonneau G (Prévention du Risque d'Embolie Pulmonaire par Interruption Cave Study Group). 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*. 1998; **338**(7): 409-15.
2. PREPIC Study Group. Eight-year follow-up of patients with permanent vena cava filters in the prevention of pulmonary embolism: the PREPIC (Prévention du Risque d'Embolie Pulmonaire par Interruption Cave) randomized study. *Circulation*. 2005; **112**(3): 416-22.



The database form

British Society of Interventional Radiology
United Kingdom Caval Filter Registry
Page 1; Version 1.0

Demographics and other identifiers	
Unique patient-identifier	
Date of birth	dd / mm / yyyy
Gender	☐ Male ☐ Female ☐ Unknown
Hospital code	select from dropdown list
Consultant code	
Date of filter placement	dd / mm / yyyy
Medication	
Anticoagulation	☐ No ☐ Yes
Type of anticoagulant	☐ Warfarin ☐ LMWH ☐ Other
Proposed duration of anticoagulation	☐ Temporary ☐ Permanent
Indications for procedure	
Indication	☐ PE despite anticoagulation ☐ PE with contra-indication to anticoagulation ☐ DVT / PE plus limited cardio-pulmonary reserve ☐ DVT with high risk of embolism ☐ Paradoxical emboli ☐ DVT with contra-indication to anticoagulation ☐ Adjunct to lysis ☐ Prophylaxis in high-risk patient ☐ Pre-operative with acute DVT / PE ☐ Pregnant with DVT / PE ☐ Other
Details of other indication	
Prophylaxis in high risk patient	☐ Head / spina injury / paraplegia / prolonged immobility ☐ Major trauma ☐ Bariatric surgery ☐ Hypercoagulable state ☐ Malignancy ☐ Pre-operative with no acute DVT / PE
Extent of acute DVT	☐ None ☐ Iliac ☐ Calf ☐ IVC ☐ Femoro-popliteal ☐ Upper limb
Free-floating/non-adherent DVT evidence	☐ No ☐ Yes
Severity of acute PE	☐ None known ☐ Minor - no haemodynamic disturbance ☐ Major - tachycardia and / or hypertension ☐ Catastrophic - requiring embolectomy

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Page 2; Version 1.0



Unique patient-identifier

Date of filter placement

Placement intention

Placement intention

- | | |
|---------------------------------|----------------------------------|
| ☐ Permanent | ☐ Conversion |
| ☐ Temporary | ☐ Undecided |

Operator grade

- | | |
|----------------------------------|--|
| ☐ Consultant | ☐ Specialist registrar |
| ☐ Fellow | ☐ Other |

Operator experience of IVC filters

- | | |
|-----------------------------|---------------------------|
| ☐ <10 | ☐ >25 |
| ☐ 10-25 | |

Caval diameter at landing site

Approach

- | | |
|-------------------------------------|-------------------------------------|
| ☐ Right jugular | ☐ Right femoral |
| ☐ Left jugular | ☐ Left femoral |
| | ☐ Other |

Details of other approach

Make & type of device

- ☐ B Braun VenaTech LGM IVC filter
- ☐ B Braun VenaTech LP IVC filter
- ☐ B Braun Tempofilter IVC filter (retrievable)
- ☐ B Braun Convertible IVC filter
- ☐ Bard G2 IVC filter
- ☐ Bard recovery IVC filter (retrievable)
- ☐ Boston Greenfield IVC filter
- ☐ Cook Birds Nest IVC filter
- ☐ Cook Celect IVC filter (retrievable)
- ☐ Cook Gunther Tulip IVC filter (retrievable)
- ☐ Cordis OptEase IVC filter (retrievable)
- ☐ Cordis TrpEase IVC filter (retrievable)
- ☐ Pyramed ALN IVC filter (retrievable)
- ☐ Simon Nitinol IVC filter

Operator experience of specific IVC filter

- | | |
|-----------------------------|---------------------------|
| ☐ <10 | ☐ >25 |
| ☐ 10-25 | |

Location

- | | |
|---------------------------------------|---------------------------------------|
| ☐ Infra-renal IVC | ☐ Supra-renal IVC |
| ☐ Juxta-renal IVC | ☐ Other |

Details of other location

Filter orientation

- | | |
|-----------------------------------|--|
| ☐ Tilted | ☐ Apex abutting caval wall |
| ☐ Centralised | |



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Page 3; Version 1.0



Unique patient-identifier	
Date of filter placement	dd / mm / yyyy
Indications for procedure ...	
Did filter deploy as planned	☐ No ☐ Yes ⁱ
Reason filter did not deploy as planned	☐ Failed to deploy ☐ Failed to open properly ☐ Perforation ☐ Other
Details of other reason filter did not deploy	
Insertion complication	☐ None ☐ Embolisation ☐ Access site vein thrombosis ☐ Sepsis ☐ Haematoma ☐ Other
Details of other insertion complication	
Procedure duration	☐ <30 minutes ☐ 30-60 minutes ☐ >60 minutes
Post-placement complications	
Post-procedure complications	☐ No ☐ Yes ⁱ
Filter complications	☐ None ☐ Migration >10 mm ☐ Structural failure ☐ Caval wall perforation ☐ Other
Recurrent DVT	☐ No ☐ Yes
Recurrent PE	☐ No ☐ Yes
Other complication	☐ No ☐ Yes
Complications comment / details of other complications	
Discharge details	
Patient status at discharge	☐ Alive ☐ Dead
Date of discharge / in-hospital death	dd / mm / yyyy
Cause of death	☐ Filter-related ☐ Due to PE ☐ Other causes
Details of other cause of death	



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i. Please ensure that all adverse incidents are also reported to MHRA:
by phone on 020 7084 3080;
by e-mail aic@mhra.gsi.gov.uk;
by FAX 020 7084 3109



**British Society of Interventional Radiology
United Kingdom Caval Filter Registry
Page 4; Version 1.0**



Unique patient-identifier

Date of filter placement

Retrieval / conversion details

Complete this section only if the placement intentions was one of the following:

- temporary,
- conversion or
- undecided

Was retrieval / conversion attempted

☐ No ☐ Yes

Date of retrieval / conversion attempt

Operator experience

☐ 0 ☐ 6-10
☐ 1-5 ☐ >10

Approach for retrieval / conversion

☐ Right jugular
☐ Left jugular ☐ Other

Details of other retrieval / conversion

Retrieval / conversion technique

☐ Snare ☐ Other
☐ Cone

Other retrieval / conversion technique

Technically successful

☐ No ☐ Yes

Reason for unsuccessful
retrieval / conversion

Retrieval / conversion complications

☐ No ☐ Yes ⁱⁱ

Details of retrieval / conversion
complications

Retrieval / conversion duration

☐ <15 minutes ☐ >60 minutes
☐ 30-60 minutes


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- ii. Please ensure that all adverse incidents are also reported to MHRA:
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by e-mail aic@mhra.gsi.gov.uk;
by FAX 020 7084 3109



British Society of Interventional Radiology
United Kingdom Caval Filter Registry
Page 5; Version 1.0



Unique patient-identifier								
Date of follow up	dd / mm / yyyy							
Follow up								
Complications in the last 12 months								
Relevant imaging in the last 12 months	<table border="0"> <tr> <td>☐ None</td> <td>☐ CT abdomen or thorax</td> </tr> <tr> <td>☐ Plain film</td> <td>☐ MR</td> </tr> <tr> <td>☐ Ultrasound</td> <td>☐ Venogram</td> </tr> </table>		☐ None	☐ CT abdomen or thorax	☐ Plain film	☐ MR	☐ Ultrasound	☐ Venogram
☐ None	☐ CT abdomen or thorax							
☐ Plain film	☐ MR							
☐ Ultrasound	☐ Venogram							
Evidence of filter complications	<table border="0"> <tr> <td>☐ None</td> <td></td> </tr> <tr> <td>☐ Migration >10 mm</td> <td>☐ Structural failure</td> </tr> <tr> <td>☐ Caval wall perforation</td> <td>☐ Other</td> </tr> </table>		☐ None		☐ Migration >10 mm	☐ Structural failure	☐ Caval wall perforation	☐ Other
☐ None								
☐ Migration >10 mm	☐ Structural failure							
☐ Caval wall perforation	☐ Other							
Details of other filter complications								
Recurrent DVT	<table border="0"> <tr> <td>☐ No</td> <td>☐ Yes</td> </tr> </table>		☐ No	☐ Yes				
☐ No	☐ Yes							
Recurrent PE	<table border="0"> <tr> <td>☐ No</td> <td>☐ Yes</td> </tr> </table>		☐ No	☐ Yes				
☐ No	☐ Yes							
Patient status at follow up	<table border="0"> <tr> <td>☐ Alive</td> <td>☐ Dead</td> </tr> </table>		☐ Alive	☐ Dead				
☐ Alive	☐ Dead							
Date of death	dd / mm / yyyy							
Cause of death	<table border="0"> <tr> <td>☐ Filter-related</td> <td></td> </tr> <tr> <td>☐ Due to PE</td> <td>☐ Other</td> </tr> </table>		☐ Filter-related		☐ Due to PE	☐ Other		
☐ Filter-related								
☐ Due to PE	☐ Other							





Notes



Notes



Notes

The First BSIR Inferior Vena Cava Filter Registry Report

Deep vein thrombosis (DVT) is the formation of blood clots in the veins of the leg. Prevention of DVT is a high priority of the Department of Health in England, particularly in patients undergoing hospital treatment as prolonged immobility is known to be a major risk factor for the development of DVT. Patients who develop DVT are potentially at risk of death if a large clot travels to the heart and lungs; a large clot in the lungs is known as a pulmonary embolism (PE). DVT can usually be treated successfully by the use of blood thinning drugs (anticoagulation); these drugs are usually effective in preventing the development of PE. Sometimes, however, the drugs are either ineffective or simply cannot be used because of contra-indicating factors. In such circumstances it is important to have another way of preventing blood clots from migrating to the lungs. This is exactly what an inferior vena cava (IVC) filter is designed to achieve.

Data on the use of inferior vena cava filters in the United Kingdom are limited, including the use of temporary, retrievable filters. There is currently no information on exactly how many retrievable filters are actually being recovered, nor on the complications associated with filter placement and filter retrieval. The British Society of Interventional Radiologists instituted the United Kingdom Inferior Vena Cava Filter Registry to try and gain some insight into the use of these devices across the United Kingdom.

The primary aims of this registry were:

- to assess various technical aspects of filter placement
- to determine the rate of complications during the insertion procedure
- to assess the frequency of complications whilst the filter is in place
- to measure the rate of successful retrieval

This report is primarily aimed at interventional radiologist who place the filters, but it should also be of interest to many other health professionals, especially those who refer patients for IVC filter placement: haematologists, general physicians, general and trauma surgeons.

It is not yet clear whether or not the placement of an IVC filter according to accepted guidelines is effective in the prevention of fatal pulmonary embolism; this is a question that can only be answered by a Randomised Control Trial. However, the report does provide a greatly improved understanding of the potential consequences of caval filter placement, and makes recommendations for improvement in current United Kingdom practice.



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