

Caval filters in intensive care: a retrospective study

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Aim: To evaluate the effectiveness of a caval vein filter (CVF) peri-implant monitoring protocol in order to reduce pulmonary embolism (PE) mortality and CVF-related morbidity.

Background: The reduction in mortality from PE associated with the use of CVF is affected by the risk of increase in morbidity. Therefore, CVF implant is a challenging prophylactic or therapeutic option. Nowadays, we have many different devices whose rational use, by applying a strict peri-implant monitoring protocol, could be safe and effective.

Materials and methods: We retrospectively studied 62 patients of a general Intensive Care Unit (ICU) scheduled for definitive, temporary, or optional bedside CVF implant. A peri-implant monitoring protocol including a phlebocavography, an echo-Doppler examination, and coagulation tests was adopted.

Results: In our study, no thromboembolic recurrence was registered. We implanted 48 retrievable and only 20 definitive CVFs. Endothelial adhesion (18%), residual clot (5%), cranial or caudal migration (6%), microbial colonization of the filter in the absence of clinical signs of infection (1%), caval thrombosis (1%), and pneumothorax (1%) were reported. Deep-vein thrombosis (DVT) was reported (8%) as early complication. All patients with DVT had a temporary or optional filter implanted. However, in our cohort, definitive CVFs were reserved only to 32% of patients and they were not associated with DVT as complication.

Conclusion: CVF significantly reduces iatrogenic PE without affecting mortality. Generally, ICU patients have a transitory thromboembolic risk, and so the temporary CVF has been proved to be a first-line option to our cohort. A careful monitoring may contribute to a satisfactory outcome in order to promote CVF implant as a safe prophylaxis option.

Keywords: caval vein filter, thromboembolic disease, pulmonary embolism

Introduction

Thromboembolic disease (TED) is a very common cause of death.¹⁻³ The diagnosis appears undervalued, because it is often formulated in postmortem examination.^{4,5} Clinical suspect imposes a more careful diagnosis and the research of permanent or transitory risk factors, in order to establish prophylaxis and therapy.⁶⁻²⁴ According to the literature, treatment or prophylaxis with the interruption of the inferior caval vein seems to deal with a reduction in mortality but not in morbidity, especially in the case of some caval vein filter (CVF) implants.^{25,26} High-risk patients (ie, affected by proximal deep-vein thrombosis [DVT]) who underwent CVF implant reported benefits in pulmonary embolism (PE) prevention. However, this was often counterbalanced by an excess of recurrent DVT, without any difference in mortality at two years.⁷

The first CVF was developed by Mobin-Uddin in the 1960s. Its specific function was to stop the shower emboli through the inferior caval vein not to jeopardize the microcircle. This definitive caval filter (DCF) was surgically placed across a central vein. Its mechanism of action was “to sieve” the blood flow, with a high transfilter gradient. This dealt with important complications (ie, caval vein thrombosis,



elephantiasis).¹² In the 1970s, Greenfield introduced a new filter. This was formed by steel filaments joined together in a radial and convergent way in order to form a cone that was structurally different from the one developed by Mobin-Uddin. Greenfield boasted a hydrodynamic filtering with a notable reduction of the resistances to the flow and a reduction of complications. The vortexes created by the filter would turn the shower emboli toward the center of the cone. The blood flow facilitates their fragmentation, maintaining a notable efficiency, despite the low-pressure gradient trans-filter and a consequent reduction of complications.^{27,28} In the 1980s, some new hydrodynamic filters were developed, thanks to the introduction of high biocompatible material. These devices were characterized by lower French size in order to be easily introduced in local anesthesia. The first temporary metal filter (with an estimated permanence time of only 3–4 days) was introduced too. It was indicated for the protection of surgical thrombectomy and thrombolysis. Nowadays, two kinds of CVFs are available: DCFs and retrievable caval filters (RCFs), percutaneously implanted by small French size technique.^{29–39} DCFs represent the tech-evolution of the partial interruption of caval inferior vein. Indications to the implant of such devices are recurrent PE in spite of anticoagulant therapy, permanent contraindication to a necessary anticoagulant therapy.

RCFs are divided into temporary caval filters (TCFs) and optional caval filters (OCFs). TCFs are used in patients with thromboembolic risk limited to the time of illness such as the protected thrombolysis in TED, surgically protected thrombectomy, pharmacologically impossible or ineffective therapy (conditions of transitory risk), and high-risk pathology.^{40–46} We consider the application of TCF important for anesthesia and Intensive Care Unit (ICU) patients too. OCFs are indicated for a patient with the intent of temporariness.⁴⁷ These filters can be removed after the corresponding period of cautious time, but they are able to be left in situ permanently.

Purpose

The purpose of this study was to evaluate the effectiveness of a CVF peri-implant monitoring protocol in order to reduce PE mortality and CVF-related morbidity. Furthermore, we aim at contributing through our study to a more careful identification of indications to DCF, TCF, and OCF implants.

Materials and methods

In our retrospective study, all patients who underwent implantation of a CVF in a general ICU of the University Hospital

from December 1993 to December 2013 were studied. We registered implantation of 68 filters (20 DCFs, 45 TCFs, and 3 OCFs) for a total of 62 patients (34 males and 28 females, median age 48±20.8 years). This study was conducted according to the principles established in the Declaration of Helsinki with the approval of the ethics committee of the Second University of Naples. According to indications and contraindications, we implanted DCFs, TCFs, and OCFs. In particular, two types of TCFs were used: at brief (7–10 days) or middle (6–12 weeks) permanence. The former had an external fixed catheter to the point of cutaneous emergency, which allowed the introduction of infusions directly into the filter (Prolyser®; Cordis). The latter (ie, Tempofilter II) had a subcutaneous fixing catheter implantable system (Table 1).

The permanence time of CVF was related to patient's illness, device model, and the incidence of any complications (ie, endothelial adhesion enclosing the filter and preventing the following removal, vulnerability of the catheter to infections from the outside).

To our cohort, medical anticoagulant therapy was always contraindicated or not effective. Concerning patients with DVT, our population included 54% of medical patients (one of them with systemic erythematosus lupus), 24% of cancer patients in medical treatment, 3% of cancer patients in surgical treatment, and 18% of patients undergoing a perioperative prophylaxis.

Indications to DCF implant were neurosurgery (1♂ patient who first was implanted a TCF), orthopedic surgery (3♂), trauma (1♂ patient who first was implanted a TCF), chronic obliterans arteriopathy (2♂), and DVT (7♀, 6♂). TCFs were implanted in patients reporting positive anamnesis for pregnancy (5), neurosurgery/stroke (1♂), orthopedic

Table 1 Filter models

Permanent filters

ANGIOCOR ADI®

Cordis "KEEPER" (cod 463-850/463-810) = AFI (fem)/ASI (giug):

This filter is designed for vena cava of a diameter inferior to 35 mm

Antheor DC: This filter is designed for vena cava of a diameter inferior to 30 mm

Antheor DC4®: megacave

Braun LGM-Vena Tech

Braun LPI®

Temporary filters

Cordis temporary vena cava filter Prolyser®

Braun LGT®: The maximum time in situ is 10 days

Braun Tempofilter II: The maximum time in situ is 6 weeks

Antheor TC

Optional filters

ALN®

SNF® (Simon-Nitinol Filter)

surgery (2♂, 1♀), DVT (9♀, 11♂), trauma (3♀, 11♂). The indications to OCF implant were stroke (1♀) and DVT (2♂) (Tables 2 and 3). Filters were placed percutaneously by the anesthesiologist at the bedside in the ICU with the patient under local anesthesia. Patients were premedicated with atropine 0.01 mg/kg intravenously and then locally anesthetized by administration of 0.2% of lidocaine 1 mg/kg subcutaneously. Heart rate (ECG), oxygen saturation, and arterial blood pressure were continuously monitored. An image intensifier, previous administration of contrast media through the right internal jugular vein, was used.

The post CVF implant monitoring was very important, especially for patients receiving TCFs.^{48–52} In order to prevent complications, we focused first on clinical signs and filtration conditions. Our postoperative monitoring protocol consisted of an echo-Doppler every 3–5 days and a phlebocavography before and after implantation and before removing the filter. An invasive hemodynamic monitoring was adopted in the case of TCF implant through the inferior and superior caval vein pressure evaluation: an increase of the differential caval vein pressure (>3 mmHg) was considered, according to our protocol, as an early sign of caval thrombosis. Coagulation tests (platelet [PLT], activated partial thromboplastin time [aPTT], prothrombin time [PT], international normalized ratio (INR), fibrinogen, and antithrombin [AT] III) were monitored every 12 hours to 24 hours. In the case of intravenous heparin therapy, the aPTT control was performed every 4 hours, maintaining the value >1.5 normal aPTT. Before discharge, all patients had undergone a clinical examination, an abdominal X-ray, and an ultrasound evaluation.

An abdominal radiography at days 1 and 7 and then yearly after placement was performed for the follow-up after the

Table 2 Implanted filters

DCF	Total n=20	Implantation period
Antheor DC4®	n=2	
ANGIOCOR ADI®	n=2	
Braun LGM-Vena Tech	n=9	
Braun LPI®	n=7	
TCF	Total n=45	Mean 23.49 (range 3–60) days
Cordis Prolyser	n=14	
Braun Tempofilter II	n=27	
Antheor TC	n=3	
Braun LGT®	n=1	
OCF	Total n=3	
ALN®	n=2	
SNF®	n=1	

Abbreviations: DCF, definitive caval filter; TCF, temporary caval filter; OCF, optional caval filter; SNF, Simon-Nitinol filter.

implantation of the DCF. Our study in particular, aimed at evaluating short-term (1–3 months after the implantation) and long-term (3 months to 20 years) complications.

Results

In our study, no thromboembolic recurrence was registered. DCFs implant dealt with caudal migration (5%) and cranial migration (10%) within 3 cm, without filter inclination on its axis (tilting) and, then, without loss of their function.

TCF implant dealt with the following complications: mild endothelial adhesion (18%) without any interference with the filter removal and the patient care; caval thrombosis (2.27%) pharmacologically treated with local thrombolysis; residual clot (diameter <1 cm) in the basket (6.8%); and microbial colonization of the filter in the absence of clinical signs of infection (2.27%).

Concerning OCFs (n=3), our study reported the following complications: mild endothelial adhesion without any consequences (100%); microbial colonization of the filter in the absence of clinical signs of infection (33.3%); cranial migration with filter inclination >15° on its axis (tilting); and loss of filtering function (33.3%). A filter substitution had been performed to treat this last complication, and

Table 3 Patient characteristics

Patients	n=62
Sex (female/male)	28/34
Age (years), median (range)	47.84 (15–86)
Indications to DCF	
Chronic obliterans arteriopathy	2
DVT	13
Trauma	1
Orthopedic surgery	3
Neurosurgery	1
Total DCF	20*
Indications to TCF	
DVT	20 [#]
Trauma	14 ^{##}
Orthopedic surgery	3
Neurosurgery	1
Pregnancy	5
Total TCF	45
Indications to OCF	
DVT	2
Stroke	1
Total OCF	3

Notes: *Two patients first underwent the implant of a temporary filter (Cordis Prolyser/Braun LGT®), which was later replaced with a definitive one (Antheor DC4®/Angiocor ADI). [#]One patient underwent first a temporary caval vein filter implant, which was later replaced with a definitive one; one patient underwent two times the substitution from a TCF to another TCF; one patient underwent a substitution into an OCF. ^{##}Two patients underwent a filter substitution respectively into a definitive (ANGIOCOR ADI®) and a temporary (Cordis Prolyser) caval vein filter.

Abbreviations: DCF, definitive caval filter; DVT, deep vein thrombosis; TCF, temporary caval filter; OCF, optional caval filter.

pneumothorax consequently appeared at the third day after implantation. It was quickly resolved (1 patient).

DVT incidence was 8% (5/62 patients), reported as short-time complication. Just for one patient (1.6%), it was reported as late complication, because the incidence was 2 years after filter implantation. However, it was treated and resolved without consequences. All patients with DVT had a TCF or OCF implanted. In our cohort, DCFs were not associated with DVT as complication (Table 4).

Discussion

The Department of Health in England in 2009 considered deaths from PE as preventable deaths.²³ It could be an exciting challenge to significantly reduce PE incidence by increasing awareness, thromboprophylaxis, and early mobilization. In 2011 Kopcke et al, in fact, focused on a substantial reduction in the hospital death rates due to PE from around 10% to 1% all over the last 30 years. Furthermore, the authors stated that there is a limited potential for prevention of PE mortality through greater use of CVF if the accepted criteria for filter placement are applied.⁴

In our study, a strict peri-implant but, in particular, a postimplant monitoring protocol (ie, temporized echo-Doppler with differential caval vein pressure evaluation, phlebocavography, coagulation tests, abdominal X-ray) deals with the efficacy of PE prophylaxis and treatment with CVF. That is, a reduction in mortality from PE and morbidity from CVF implant was observed in our retrospective study. Sixty-two patients were implanted a total amount of 68 CVF (n=20, DCF; n=48, RCF). Thromboembolic recurrence did not occur in any patient. Mild endothelial adhesion occurred without any interference with filter function and removal; a few cases of filter migration were registered, but only in one patient, a filter substitution became necessary. Just one

episode of caval thrombosis and one episode of residual clot were reported after TCF implant. Microbial colonization of the filter in the absence of clinical signs of infection occurred in two patients.

DVT incidence occurred only in patients with RCF implants (8%) in spite of what was reported in literature. The PREPIC randomized trial in fact reported an initial small reduction in PE, the absence of a later significant reduction in mortality associated with a higher incidence of proximal DVT in patients with permanent CVF implant.^{4,53} However, these data should be carefully analyzed and related to the concomitant anticoagulant therapy practiced. For this reason, the indications to DCF implants diminish, because of the shortness of efficacy proven (only for the first 3 months of illness).⁵⁴ Nevertheless, our study did not report any increase of occurrence in thrombotic disease in the case of permanent filter implant. Our results are consistent with the findings of Vaziri et al dealing with PE prophylaxis both by RCF and chemotherapeutics in bariatric surgery. The experience of Vaziri et al described a lower incidence of DVT, the absence of clinical episodes of PE and, in spite of a mean time to filter retrieval of 200±131 days, a lower incidence of filter complications with a successful end easy retrieval. All bariatric patients with a prior history of venous thromboembolism (VTE), hypercoagulable disorder, body mass index ≥55 kg/m², marginal pulmonary reserve, and severe immobility were considered to be at higher risk for postoperative VTE and underwent RCF placement in association with standard chemoprophylaxis.⁵⁵

Our data suggest Tempofilter II implant for transitory risk because of its longer time of permanence in situ. In most cases, we recognized the presence of the transitory risk in the genesis of the PE (surgical, traumatized, and pregnant patients), which was TCF implant in 70% of the

Table 4 Filter-related complications

Filter	Complications	Number of patients	Implantation period
DCF	Cranial migration (2 cm)	2	6–68 months
	Caudal migration (3 cm)	1	
TCF	Caval thrombosis	1	4–28 days (18.5±8.5)
	Residual clot	3	
	Endothelial adhesion	8	
	Microbial colonization of the filter in absence of clinical signs of infection	1	
	DVT	4	
OCF	Cranial migration	1	3–48 days (25.3±12)
	Endothelial adhesion	3	
	Microbial colonization of the filter in absence of clinical signs of infection	1	
	Pneumothorax	1	
	DVT	1	

Abbreviations: DCF, definitive caval filter; TCF, temporary caval filter; DVT, deep vein thrombosis; OCF, optional caval filter.

cases.^{14,15,19,42–44} The indications to TCFs both for prophylaxis and therapy of the TED increase despite the *Antithrombotic Therapy and Prevention of Thrombosis, 9th ed (AT9)*⁵⁶ suggesting not to use these devices for primary VTE prevention in patients with major trauma, general and abdominal-pelvic surgery, or major orthopedic surgery. Acute DVT of the leg, such as acute PE, is recommended to be treated with CVF only in the case of contraindication to anticoagulation (AT9, grade 1B). The AT9 suggest a conventional course of anticoagulant therapy as soon as the risk of bleeding in these patients resolves. The rationale of contemporary anticoagulant administration would not seem to be linked to the permanent caval filter implant.⁵⁶ Despite the presence of such guidelines, the literature background continue to get more and more opinions of disagreement may be because of the difficulty in sharing of opinions and experiences.⁷ Rajasekhar et al⁵⁷ underlined the presence of measurement and/or publication bias in all observational studies examined to publish their systematic review. According to the meta-analysis of observational studies in epidemiology (MOOSE) guidelines and the Newcastle Ottawa scale for quality assessment, they found the rate of PE to be statistically lower in the presence rather than in the absence of inferior CVF implant in trauma patients. These data remain biased because of the lack of contemporary pharmacologic prophylaxis described in the analyzed studies.⁵⁷ Thus, PE is thought to be the third major cause of death after trauma in patients surviving longer than 24 hours after the onset of injury, a common line of conduct remains still unclear.⁴⁷ The enthusiasm is divided on the advantages of TCFs at middle permanence, but we are so far to dispose of a device and of an applicatory control without risk. The excellent outcome was provided by a careful monitoring. This aspect limits the diffusion of the method that, otherwise, is burdened by an increase of the failures.^{58–67}

Conclusion

Our study proves the effectiveness of CVFs in TED, when anticoagulant therapy is contraindicated or not effective. Temporary risk factors play an important role in PE and, in particular, deal both on the increased and decreased indications for TCF and DCF implants, respectively. An appropriate laboratory and echo-Doppler monitoring allowed us to extend safely the time of permanence in situ of TCF. In the past few years, the indications for the use of the CVF underwent a critical revision accompanied by a therapeutic restriction especially for the DCF. The indications for the TCF show an increasing extension with regard to the coverage of the transitory risk,

where the time of permanence of the RCF is increased to 6 weeks. Thanks to the accurate monitoring, TCF permanence in situ has been longer, according to clinical needs. A lot of conditions of transitory risk (ie, major trauma, pregnancy, orthopedic surgery, major surgery) have a time of protection demanding longer than the maximum time of filtration of the first removable filters. We proved the time of permanence in situ among the TCFs and the OCFs to be significantly different (days: 18.5 ± 8.5 vs 25.2 ± 11.6 , respectively). We did not prefer to use DCF because of both the limited indications in our population and the lack of literature recommendation.

Among TCFs, the Tempofilter II allows a longer protection and a simple management but is contraindicated for thrombolysis.

More polycentric clinical trials are needed to better evaluate indications for caval filtration in order to give this approach enhanced safety, efficacy, and propagation.

Disclosure

The authors report no conflicts of interest in this work.

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