

# Inferior Vena Cava Filters in Hemodynamically Unstable Patients with Acute Pulmonary Embolism: How Often are They Used? Data from Multicenter Prospective Registries on Acute Pulmonary Embolism

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**Abstract** The use of inferior vena cava (IVC) filters is recommended in patients with acute pulmonary embolism (PE) who have absolute contraindications to anticoagulant drugs and/or in those subjects with recurrent PE despite treated with an adequate anticoagulant regimen. During the last 2 decades, some investigations have demonstrated that the use of IVC filters in high-risk PE patients, treated or not with systemic thrombolysis, was able to reduce the short-term mortality rate if inserted early after the acute event. The aim of the present review is to analyze the use of IVC filters in high-risk PE patients enrolled in prospective multicenter registries between 1990 and 2018. After screening 3542 article in PubMed, Scopus, Cochrane library and Goggle Scholar databases, we identified four registry studies meeting the inclusion criteria. In a prospective cohort of 39,056 patients, 1387 (3.5%) were hemodynamically unstable at admission. Among them, IVC filters were used only in 2.7% of cases. Conversely, IVC filters were inserted in 3.8% of hemodynamically stable patients. Over the years, a fluctuating trend in the use of IVC filters was observed. In the absence of randomized controlled trial on this issue, which would be difficult, if

not impossible to realize, data obtained from the medical literature seem to suggest that IVC filters could represent a valid adjunctive therapy in hemodynamically unstable PE patients, able to prevent further hemodynamic deterioration. Further and larger subgroup analyses, obtained both by prospective and retrospective studies, are necessary to clarify this therapeutic approach.

**Keywords** Pulmonary embolism · High risk · Massive · Reperfusion treatment · Inferior vena cava filters

## Introduction

Acute pulmonary embolism (PE) still represents the third leading cause of cardiovascular mortality in western countries [1, 2]. Patients hemodynamically unstable at presentation are classified by the European guidelines on the management of acute PE as high risk, due the higher risk of mortality in the short-term period and especially over the first hours [3–6]. These subjects need, as soon as possible and in the absence of absolute contraindications, a reperfusion treatment, generally represented by systemic thrombolysis (ST) [5, 6]. Inferior vena cava (IVC) filters are currently suggested in patients with acute PE who have absolute contraindications to anticoagulant drugs and/or those with recurrent PE despite an adequate anticoagulant treatment [5]. Over the latest years, several investigations have reported an overuse of IVC filters associated with a relatively low rate of retrieval [7]. At the same time,

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different large studies have suggested that the use of IVC filters in hemodynamically unstable PE patients, treated or not with ST, was able to improve the short-term survival, especially when inserted early after the acute event [8–11]. Unfortunately, no randomized clinical trials (RCTs) have been conducted on this issue. The reasons are multifactorial, such as the relatively low number of high-risk PE patients, which represent less than 5% of all PEs, and ethical reasons [8]. Indeed, it may not be feasible and either unethical to conduct RCTs in this clinical scenario since many patients would be excluded due to contraindications to IVC filters and at the same time it would not be ethical to randomize patients dying from high-risk PE. To overcome these limitations, the analysis of multicenter prospective registries could be an alternative solution to assess the management of a disease in daily clinical practice. For these reasons, in the present manuscript, we aimed to review and analyze the use of IVC filters in high-risk PE patients, enrolled in prospective multicenter registries between 1990 and 2018.

## Materials and Methods

### Literature Search

A literature search based on PubMed (MEDLINE), Scopus, Cochrane library and Google Scholar databases was performed to locate prospective registry studies, in English language, reporting data of hemodynamically unstable PE patients treated with IVC filters, from January 1990 to January 2019. We used a combined text word and MeSH (Medical Subject Headings) search strategy. More precisely, the following combination of keywords was used: “Inferior vena cava filters pulmonary embolism,” “Inferior vena cava filters pulmonary embolism registries,” “Inferior vena cava filters massive pulmonary embolism” and “Inferior vena cava filter unstable pulmonary embolism.” Moreover, we searched the bibliographies of target studies for additional references.

### Study Selection and Data Extraction

Titles and abstracts retrieved from the search were reviewed. Articles were included if (a) they reported the results of a prospective registry on acute PE; (b) it was a multicenter study; (c) patients have an objectively confirmed diagnosis of acute PE; (d) the number of patients hemodynamically unstable was presented; and (e) data on the use of IVC filters in hemodynamically unstable patients were provided. RCTs were excluded from the analysis. Final determination of article inclusion was based on consensus by authors. Extracted data included number of

patients enrolled in the registry, number of patients hemodynamically unstable, definition of hemodynamic instability, mean age (when available), concomitant presence of deep vein thrombosis (DVT), number of IVC filters inserted, reperfusion treatment as ST, catheter-directed treatment (CDT) and surgical embolectomy (SE), follow-up duration, mortality for all causes and PE-related (when available).

## Literature Results

### Article Selection and Registries Included in the Analysis

A total of 3542 articles were identified. After excluding the duplicates obtained using the different searching MeSH ( $n = 1821$ ), 1710 articles were screened and then excluded for not meeting inclusion criteria due the article type (editorial, review article, meta-analysis) or its design (single-center investigation, retrospective design, trial) or article not in English language. As result, 11 articles were assessed for eligibility and carefully reviewed (Fig. 1). Of them, seven were excluded because they did not provide data on the use of IVC filters in high-risk PE patients [12–18]. Finally, four study registries met the inclusion criteria and were included in the analysis (Table 1). The following registries were used: International Cooperative Pulmonary Embolism Registry (ICOPER) [19], Emergency Medicine Pulmonary Embolism in the Real-World Registry (EMPEROR) [20], perfil de riESgo de los Pacientes con ETV en Hospitales Españoles atendidos en los seRvicios de urgencias e Impacto Asistencial (ESPHERIA) [21] and Registro Informatizado de Enfermedad TromboEmbólica (RIETE) registry [22].

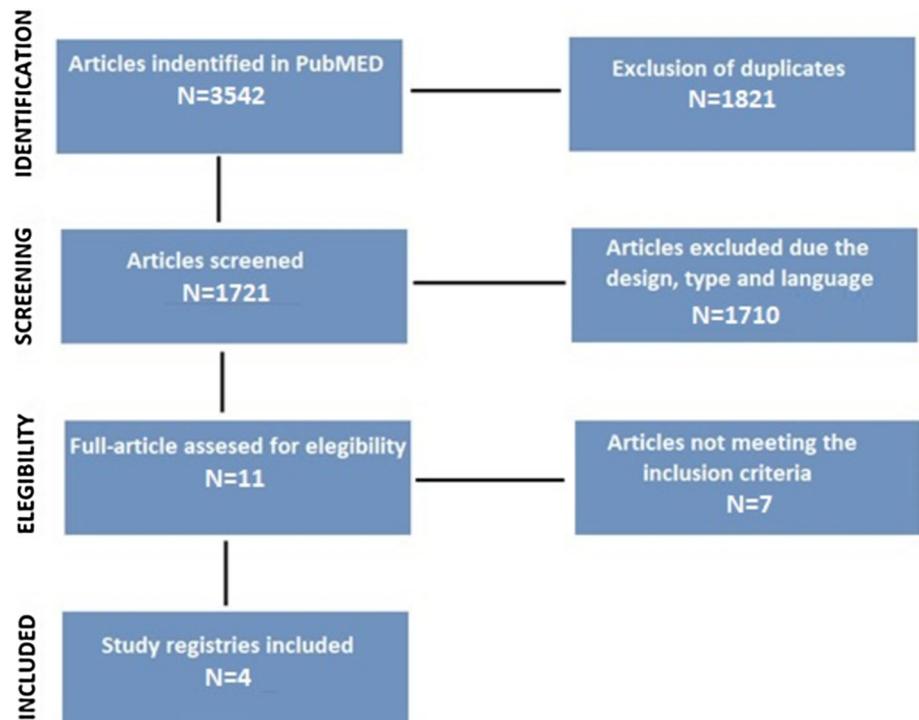
### Population

The identified study registries enrolled prospectively 39,056 patients with acute PE between 1993 and 2016. Among these, 1387 (3.5%) were hemodynamically unstable at presentation (Fig. 2). The mean age of patients, calculated using the data of three of four registries ( $n = 1373$ ), was 65.1 years [19, 20, 22]. Among them, 54.8% (465/848) had a concomitant DVT [19, 20, 22].

### IVC and Reperfusion Treatment

Data regarding the use of IVC filters were available in all the studies reviewed as per inclusion criteria. During the study period, 38 hemodynamically unstable PE patients (2.7%) received an IVC filter (Table 1). The trend regarding the implantation of an IVC filter over the years of

**Fig. 1** Flowchart of the searching method adopted to identify the study registries included in the review



enrollment of the four different multicentric registries shows some fluctuations. The larger use was observed in the EMPEROR [20] registry while no patients were treated in the ESPHERIA [21] (Fig. 3). However, the relatively low number of patients enrolled in the latter could represent a potential bias in the evaluation of IVC filters use.

Reperfusion treatments were generally underused in the population analyzed. Indeed, ST was administered in 18.8% of hemodynamically unstable patients ( $n = 261$ ), while CDT and SE were used in 0.5% ( $n = 7$ ) and 2.2% ( $n = 31$ ) of cases.

### Short-Term Mortality

The mortality rate for all causes was 16.7% while that on PE-related mortality based on three of four registries was 66.5% [19, 20, 22]. Unfortunately, three of the four registries did not provide any data regarding the short-term outcome related to the use of IVC filters [20–22]. Only the ICOPER registry reported that hemodynamically unstable patients treated with an IVC filter were younger compared to those treated without and none of the former developed a recurrent PE over the following 90 days. Moreover, IVC filter patients showed a survival rate of 90.9% over the follow-up period. Conversely, those patients treated without an IVC filter developed a recurrent PE in 13.4% of cases while the survival rate was 56.7% [19].

### Literature Results

Our analysis demonstrates that IVC filters were inserted in 2.7% of hemodynamically unstable patients with acute PE enrolled in prospective multicenter registries between January 1990 and January 2019. Conversely, in subjects hemodynamically stable at admission, IVC filters were used in 3.8% of cases. Moreover, the trend in the use of IVC filters showed a significant fluctuation over the years. Unfortunately, no data regarding the type of filters, intra- or post-procedural complications and retrieval rates were provided by the reviewed investigations. Previous studies have already demonstrated that IVC filters significantly reduce the risk of embolization from DVT into the pulmonary circulation, despite an adequate anticoagulant regimen [23–27]. Moreover, the potential benefit of IVC filters in hemodynamically unstable PE patients has been already demonstrated in large retrospective analyses, raising the question whether this interventional approach could be considered as an adjunctive therapy for the salvage therapy of these patients. [8–10, 24]. Indeed, Stein et al., after analyzing a cohort of more than 2 million patients, demonstrated that the use of IVC filters in patients with hemodynamic impairment was associated with a very significant reduction of case fatalities, especially when associated with thrombolytic treatment (85% of reduction). These results were confirmed regardless of the use of systemic reperfusion, maintaining a significant reduction in the mortality rate (42%) [27]. Another investigation

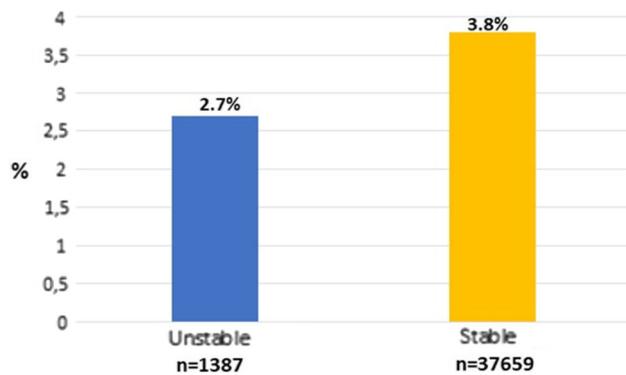
**Table 1** Characteristics of patients enrolled in the reviewed registries

Registry	Year of publication	Entire population	Patients hemodynamically unstable N (%)	Hemodynamic instability definition	Mean age (years)	Concomitant DVT N (%)	IVC N (%)	Reperfusion N (%)	Thrombolysis		Follow-up	Mortality (all cause)	Mortality (PE-related)
									CDT	SE			
ICOPER [19]	2006	2392	108 (4.5)	SBP < 90 mmHg	64	34 (32.3) <sup>a</sup>	11 (10.1)	33 (30.5)	1 (0.9)	3 (2.7)	90 days	51 (51.8)	35 (62.5)
EMPEROR [20]	2012	1875	58 (3.0)	SBP < 90 mmHg	63.3	13 (22.4)	9 (15.5)	7 (12.1)	0	2 (3.4)	In-hospital	8 (13.8)	3 (37.5)
ESPHERIA [21]	2017	399	14 (3.5)	ESC classification	NS	NS	0	4 (28.5)	0	NS	In-hospital	0	NS
RIETE [22]	2018	34,380	1207 (3.5)	SBP < 90 mmHg for > 15 min.	68.1	418 (61.0) <sup>b</sup>	18 (7.6)	217 (17.9)	6 (0.5)	26 (2.2)	30 days	168 (13.9)	113 (67.2)

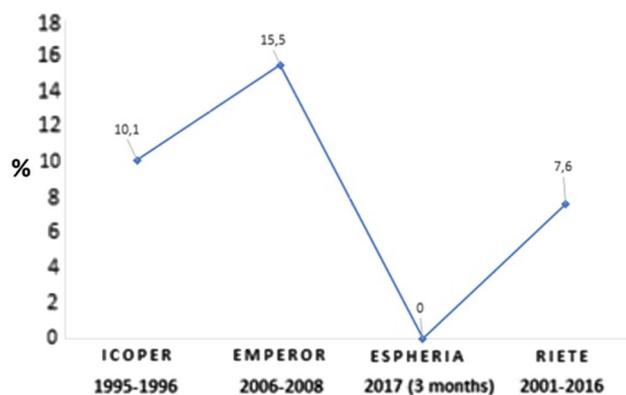
DVT deep vein thrombosis, IVC inferior vena cava filter, PE pulmonary embolism, SBP systolic blood pressure, ESC European Society of Cardiology, CDT catheter-directed therapy, SE surgical embolectomy

<sup>a</sup>Referred to 105 patients

<sup>b</sup>Referred to 685 patients



**Fig. 2** Comparison on the use of inferior vena cava filters in hemodynamically unstable and stable patients enrolled in the four registries reviewed



**Fig. 3** Trend in the use of inferior vena cava filters in hemodynamically unstable patients enrolled in multicenter prospective registries on acute pulmonary embolism

performed by the same authors demonstrated a significant effect of IVC filters on the short-term mortality rate for all causes in patients aged more than 80 years old [28]. Similar results were provided by Wadhwa et al., who reported a lower all-cause mortality rate in massive PE patients treated with IVC filters versus those treated without (24.8 vs 40.9%), estimating an absolute risk reduction of about 16% [29]. In more recent years, Stein et al. highlighted the importance of the timing of IVC filters insertion in hemodynamically unstable patients. Indeed, they demonstrated that mortality was lower in those treated with IVC filters within the first or second day after admission, suggesting that also the use of IVC filters in PE patients could be considered as a “matter of time” as for the use of ST [8–10]. Moreover, they demonstrated that both thrombolytic treatment and IVC filters were underused in hemodynamically unstable patients, despite able to save life [28, 29]. These data were partially confirmed also by our analysis, since very few patients received an IVC filter in real-world clinical practice. Bikdeli et al. [30] reported a lower in-hospital mortality in patients hemodynamically

unstable not receiving thrombolysis treated with IVC filters versus those without (33 vs 51%). Similarly, in those treated with thrombolytic therapy, the use of IVC filter was associated with a better outcome when compared with those without IVC filters (8% vs 18%).

### Inferior Vena Cava Filters in Hemodynamically Unstable PE Patients: Available Recommendations

European guidelines on the management of acute PE do not recommend the insertion of IVC filter as a primary treatment in patients hemodynamically unstable at admission [5, 6]. It is also true that it would be very difficult to conduct adequate randomized trial, either for ethical reasons and/or difficulties in recruiting adequate number of patients [8, 31]. From a pathophysiological point of view, IVC filter use may be appropriate in patients who are hemodynamically unstable at presentation to prevent a further hemodynamic decompensation due to “embolic poussèè,” or better to further embolic migrations into the pulmonary circulation [32, 33]. Doubtless, better understanding of the effect of IVC filter in these patients would require more patient-level data. Potential benefits of IVC filters in hemodynamically unstable patients have been highlighted also by different international guidelines. The American Heart Association recommendations on the management of PE stated that the placement of “an IVC filter may be considered for patients with acute PE and very poor cardiopulmonary reserve, including those with massive PE (Class IIb; Level of Evidence C)” [32]. Similarly, the guidelines of the America College of Radiology suggested the use of IVC filters in hemodynamically unstable patients who have undergone pulmonary thrombolysis or surgical embolectomy [33].

### Discussion

As demonstrated by our analysis, the issue has been poorly investigated using prospective multicenter registries since only the ICOPER study reported a sub-analysis on the issue [19]. Moreover, since no data were presented on the outcome of those patients treated with an IVC filter in the other reviewed registries, we cannot make any considerations on this topic. Moreover, the aim of the manuscript was to assess the use of IVC filters in hemodynamically unstable PE patients and not to analyze their effects on the short-term mortality. However, we reported the mortality rates on hemodynamically unstable PE patients in the review for major clarity and to give a picture of the population enrolled in each registry. To notice also that registries not explored the potential complications due to the

IVC filters insertion as well its retrieval in the long-term period, suggesting a low interest in this type of sub-analysis despite available evidences suggest interesting results. In this regard, the potential power of prospective registries is often underestimated despite representing one of the few potential sources of data for these patients, after the retrospective analysis often based on the “The International Classification of Diseases” (ICD) which is not exempt by intrinsic errors due a potential incorrect codification of the diseases by the physicians. As a matter of a fact, current data do not allow to affirm that the use of IVC filters improves the outcome in hemodynamically unstable patients. Doubtless, further subgroup analysis in the future based on multicenter prospective registries will be helpful to shed more light on this matter.

### Limitations

Our review has some limitations. Firstly, all the baseline conditions were not systematically reported by the studies reviewed. Secondly, data regarding mortality in hemodynamically unstable patients in some cases were missing. Moreover, only one registry assessed the role of IVC filters on the short-term mortality. It is also true that in our review we did not want to assess the impact of IVC filters on the short-term outcome, but to describe their use using real-world data based on larger multicentric registries.

### Conclusions

IVC filters are used in about 3% of hemodynamically unstable patients enrolled in multicentric prospective registries on acute PE. Furthermore, over the years, a fluctuating trend in the use of IVC filters was observed and generally the devices were inserted in patients hemodynamically stable at admission. In the absence of randomized controlled trial on this issue, which would be difficult, if not impossible to realize, data obtained from the medical literature seem to suggest the use of IVC filters as adjunctive therapy in hemodynamically unstable PE patients. Further and larger subgroup analysis, obtained by both prospective and retrospective analyses, is necessary to clarify this therapeutic approach. However, interventionist might be aware that IVC filter may represent an adjunctive tool that may assist salvage therapy in hemodynamically unstable PE patients.

### Compliance with Ethical Standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical Approval** This article does not contain any studies with human participants or animals performed by any of the authors.

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