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Bedside implantation of a new temporary vena cava inferior filter - Safety and efficacy results of the European ANGEL-Registry

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ABSTRACT

Purpose: Pulmonary embolism (PE) is a frequently occurring complication in critically ill patients. Simultaneous occurrence of PE and life-threatening bleeding, may render medical anticoagulation impossible. For these patients, inferior vena cava filters (IVCF) present a valuable therapeutic alternative. The Angel® catheter is a novel IVCF that provides temporary protection from PE and is implanted at bedside.
The primary objective of the European Angel® catheter registry is to evaluate the safety and efficacy of this IVCF.
Material and methods: The European Angel® catheter registry is an observational, multi-centre registry. Patients from four countries and eight sites that have undergone Angel® catheter implantation between March 2013 and February 2017 were enrolled.
Results: A total of 114 critically ill patients were included. The main indication for implantation was a high-risk for PE in combination with contraindications for anticoagulation (69.3%). One clinically non-significant PE (0.9%) occurred in a patient with an indwelling Angel® catheter. No cases of catheter associated serious complications were observed.
Conclusion: Data shows that the Angel® catheter is a safe and effective approach to overcome the acute phase of critically ill patients with a high risk for the development of PE or an established PE, when an anticoagulation therapy is contraindicated.

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Abbreviations: CTA, computed-tomography angiography; cCT, cranial computer tomography; DVT, deep vein thrombosis; ICU, intensive care unit; IVCF, inferior vena cava filters; LMWH, low molecular weight heparin; PE, Pulmonary embolism; TP, thrombosis prophylaxis; UH, unfractionated heparin; VTE, venous thromboembolism.

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1. Introduction

Critically ill patients admitted on intensive care unit (ICU) exhibit a high risk for both deep vein thrombosis (DVT) and concomitant pulmonary embolism (PE). In these patients, PE manifests most commonly with a delay between the fifth and the seventh day after admittance, while DVT occurs early after the admission on ICU [1,2]. Consequently, the early administration of thrombosis prophylaxis is of major importance to prevent venous thromboembolism (VTE) [2,3].

In patients with a high risk for bleeding or active bleeding, anticoagulants for thrombosis prophylaxis or therapeutic anticoagulation may be contraindicated [4,5]. This subset of patients usually consists of patients with trauma, profound gastrointestinal bleeding, intracerebral hemorrhage or bleeding in other vital organs, where further anticoagulation may cause life-threatening events. In order to prevent major bleeding incidents by withdrawing anticoagulation, the implantation of temporary or permanent inferior vena cava filters (IVCF) presents a therapeutic option, balancing the risk for PE and bleeding complications (3,6,7). Accordingly, IVCFs are endorsed by the European Society of Cardiology (ESC) in patients with acute PE and absolute contraindications to anticoagulation with a class IIa recommendation in the current guidelines for the treatment of acute PE [6]. The Angel® catheter (BiO_2 Medical Inc., San Antonio, TX, USA) is a novel temporary IVCF, allowing a simple bedside placement without fluoroscopy. It provides a fast and reliable PE protection in patients in which the administration of anticoagulation or traditional IVC filters are contraindicated [7,8].

The purpose of the European ANGEL-Registry was to evaluate the safety and efficacy of the Angel® catheter in critically ill patients at increased risk of PE or with manifest PE and contraindications for prophylactic or therapeutic anticoagulation.

2. Materials und methods

2.1. Study design and patient population

The European ANGEL Registry (NCT 02917135) is a retrospective, observational, multi-center registry including patients from four European countries (Great Britain, Germany, Italy, Belgium) and eight centers. Patients admitted on ICU that underwent Angel® catheter implantation between March 2013 and February 2017 were enrolled in the present study. Inclusion criteria were patients 18 years or older, admitted on internal, surgical or neurological ICU that received an Angel® catheter on grounds of a high risk for PE or a proven PE in combination with an absolute contraindication for prophylactic or therapeutic dosing of anticoagulation.

High risk for PE was defined as presence of hypercoaguable states either primary (e.g. antithrombin III, protein C and S deficiency, resistance to activated protein C and hyperhomocysteinaemia, Factor-V Leiden mutation or prothrombin mutation), or secondary (e.g. immobility, surgery, trauma, malignancy or limb paralysis).

PE was diagnosed by a computed-tomography angiography (CTA) showing filling defects in the pulmonary artery or in its branches resembling thrombus material by an experienced radiologist. CTA was performed in patients suspected of having PE on admittance (Geneva-Score ≥2, with intermediate to high pretest probability) and in patients who developed specific signs and symptoms of PE during their ICU stay [9].

Contraindication against prophylactic or therapeutic anticoagulation was stated as presence or high probability of intracranial bleeding, major active gastrointestinal or surgical life-threatening bleeding or any other active or threatening bleeding event with potentially serious or life-threatening consequences.

Exclusion criteria for implantation were defined as pregnancy, body mass index >45 kg/m^2, known IVC diameter of >30 mm or <15 mm, pre-existence of a permanent IVCF, functioning pelvic renal allograft on the side available for the device insertion, patients that have undergone surgical procedure that involved the femoral vein or pelvic veins through which the device should be inserted and known hypersensitivity to the Angel® catheter contains (nitinol, nickel or titanium), and infection of the insertion site.

This study was conducted in compliance with the Declaration of Helsinki with regard to investigation in human subjects and the local Ethics Committees of the respective sites approved the study protocol. The need for informed consent was waived due to the retrospective nature of the registry.

2.2. Design of the Angel® catheter

The Angel® catheter combines the functions of an IVCF and a trilumen central venous catheter (Fig. 1). The filter is positioned in the IVC through the femoral vein and serves as an emboli protection device. It has a length of 35 cm and a 9 F outer sheath diameter and is intended for a use shorter than 30 days. The conical, self-expanding, nitinol filter has wide proximal openings that allow the capture of clots in the distal end of the filter and features a maximum expanded diameter of 30 mm. The device meets the requirements of the applicable EC directives and is certificated with CE marking (Angel® catheter CE 0088 and Angel® catheter Accessory Kit CE 0086).

2.3. Implantation of the Angel® catheter

The implantation of the Angel® catheter was performed according to the manufacturer's instruction. Briefly, after the application of local anesthesia, the puncture of a femoral vein (either right or left) was conducted under ultrasound guidance when available and a guiding-wire was inserted in Seldinger technique. The initially collapsed IVCF was then deployed into the IVC over the wire and the filter was finally expanded in the vessel lumen. The insertion depth of the filter determining the final position of the catheter tip (below L1–L2 and above L4–L5) was decided upon by the height of the patient and the according reading of a reference table provided by the manufacturer. Following the

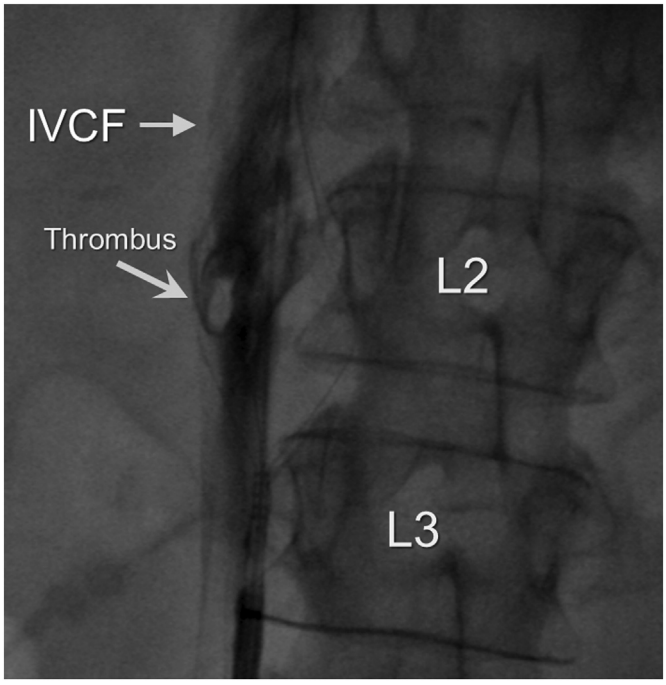

Fig. 1. Device description. The Angel® catheter has a self-expanding nitinol filter permanently attached to a triple-lumen central venous catheter with ports proximal, within, and distal to the filter. Both the sheath and the catheter are flexible, kink-resistent and made of polyether block amide resins (Pebax; Arkema Inc., King of Prussia, Pennsylvania).

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