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Regular Article

Role of prophylactic filter placement in the endovascular treatment of symptomatic thrombosis in the central veins

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ABSTRACT

Objectives: To evaluate the role of filter implantation in reducing the incidence of fatal pulmonary embolism during the endovascular treatment of thrombosis in the major tributary of the superior vena cava (SVC).
Methods: From October 2004 to October 2008, we conducted a cohort study of 40 patients with thrombosis of the central veins who were preparing for endovascular interventions and received or did not receive filter. The symptom scores were measured, the incidence of pulmonary embolism (PE) was observed, and patient follow-up studies were conducted for three years.
Results: One week after therapy, the symptom score improved in both groups compared with before therapy ($P<0.001$), but no significant difference was found between the scores of the two groups ($P>0.05$). Four patients in the control group died from PEs after therapy, but no patients in the filter group presented evidence of PE. The survival rates at 1, 2, and 3 years (72.9%, 50%, and 27.1%, respectively) for the filter group were higher than those for the control group (47.6%, 19.0% and 14.3%, respectively; $P=0.015$). The survival time of patients in the filter group with bronchogenic carcinoma (18 ± 2 months) was longer than that of the patients in the control group (12 ± 2 months) after the endovascular treatment ($P<0.001$).
Conclusions: Prophylactic filter placement could be a safe and effective method for preventing PE in pre- or post-endovascular-treated patients with thrombi in their central veins.

Introduction

Thrombosis in the central veins may be caused by central venous catheters, pacemaker wires, fibrosing mediastinitis, and thoracic aneurysms, but it most frequently results from the growth of a malignant tumor, often a bronchogenic carcinoma, and subsequent venous compression [1–3]. Surgery plays a limited role in the management of patients with thrombosis of the central veins secondary to malignancy because operations to remove the obstruction are associated with advanced disease [4]. Endovascular techniques have become the first-line therapy, providing a prompt resolution of the vessel obstruction in 75% to 95% of patients with thrombosis of the central veins [4]; furthermore, this treatment is able to immediately alleviate such symptoms as facial swelling [4,5].

Using thrombolytic agents or endovascular techniques to dissolve or remove the thrombus carries the risk of a fatal pulmonary embolism (PE) [5]. The aim of this study was to evaluate the role of filter implantation in reducing the incidence of fatal pulmonary embolism during the endovascular treatment of thrombosis in the major tributary the superior vena cava (SVC).

Methods

Ethical Approval for Research

This study was approved by the Ethics Committee of the Bethune International Peace Hospital, China and conducted in accordance with Declaration of Helsinki. Following the requirements of the hospital ethics committee, all of the patients provided written informed consent forms prior to the treatment.

Study Design and Setting

From October 1, 2004 to October 1, 2008, totally 108 patients with thrombosis in the central veins who were preparing for endovascular interventions were recruited in our department. Exclusion criteria included the following: (1) the patients' total score for signs and symptoms was not higher than 4 (Table 1); (2) patients who presented a

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Table 1
Scoring system for the signs and symptoms of SVC syndrome.

Signs and Symptoms	Grade
Neurologic symptoms	
Stupor, coma, or blackout	4
Blurry vision, headache, dizziness, or amnesia	3
Changes in mentation	2
Uneasiness	1
Laryngopharyngeal or thoracic symptoms	
Orthopnea or laryngeal edema	3
Stridor, hoarseness, dysphagia, glossal edema, or shortness of breath	2
Cough or pleural effusions	1
Nasal and facial signs or symptoms	
Lip edema, nasal stiffness, epistaxis, or rhinorrhea	2
Facial swelling	1
Venous dilatation	
Neck vein or arm vein distention, upper extremity swelling, or upper body plethora	1

Note: The patient's total score for signs and symptoms was calculated as the sum of the highest scores in each class.

thrombosis in the SVC indicated by CTA; (3) patients who declined to participate in the study; (4) patients with a lower-extremity deep venous thrombosis; and (5) patients who presented a pulmonary embolism (PE) with pulmonary CTA.

After exclusion of 34 patients, the remaining 74 patients were divided into two treatment groups by using a computer-generated randomization list, including the filter group with 38 patients and the control group with 36 patients (Fig. 1).

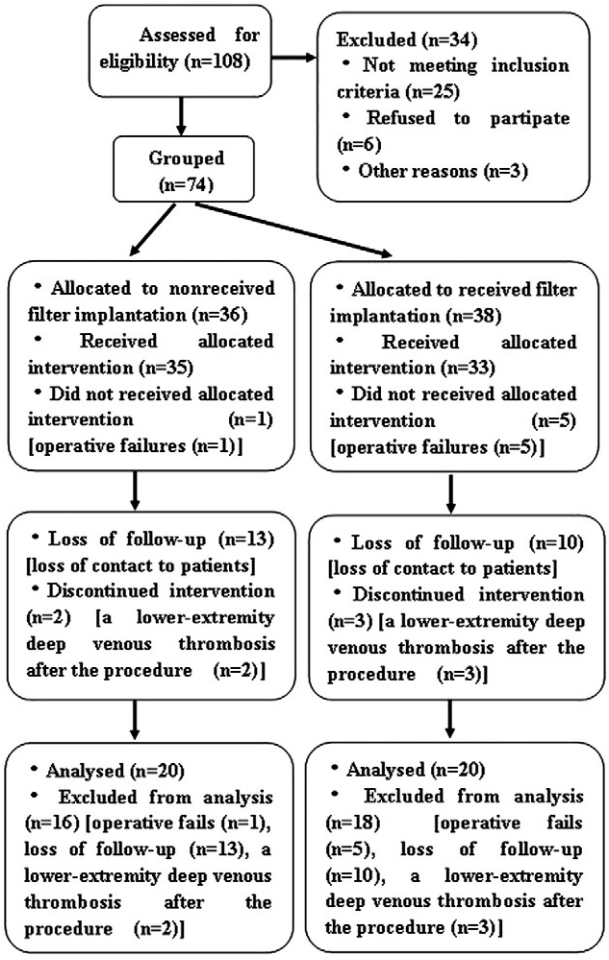

Fig. 1. Flow diagram of patient allocation.

Filter Implantation

All of the filters (Braun Medical, France) were placed via the femoral approach by an experienced interventional radiologist. All of the filters were retrievable. All of the procedures were undertaken using standard sterile techniques and 1% xylocaine as the local anesthetic. All filter deployments and retrievals were undertaken under fluoroscopy. The filter was retrieved when the thrombus of the SVC was completely eliminated, and no significant trapped thrombus was observed with CTA. A venogram was performed at the time of retrieval. The filter was retrieved via the femoral approach. We snared and removed the initial filter with an 11 Fr coaxial retrieval system.

Endovascular Interventions

All of the patients received pulse spray thrombolysis with recombinant tissue plasminogen activator (rt-PA) via a Uni-fuse Infusion catheter (AngioDynamics, USA), followed by balloon (Boston Scientific, USA) pre-dilatation and stent (self-expandable, Boston Scientific, USA) implantation.

The patients were monitored using continuous pulse oximetry and ECG during the procedure. All of the patients were heparinized using an intravenous infusion of 200 U/kg before therapy, and 5000 units of low-molecular-weight heparin was injected subcutaneously every 12 hours after the therapy while the patient was in the hospital. We prescribed lifelong anticoagulation with 5000 units of low-molecular weight heparin injections every 24 hours after discharge from the hospital.

Observed Index

Each sign or symptom of SVC syndrome was given a qualitatively weighted grade [6](Table 1), and the total scores for the signs and symptoms of SVC syndrome for the patients in the two groups were recorded and analyzed before and 1 week after the therapy. These symptom scores were assigned before and after the intervention by the same radiologist, and the same respiratory physician provided identical ratings. All recruited patients were reobserved with CTPA after the procedure.

Follow-up

All of the patients underwent postoperative follow-up over the course of 3 years, and the safety and efficacy outcomes (e.g., death, severe bleeding, in-stent restenosis, pain, fever, stent migration, in-stent thrombosis) were observed. The survival rates were determined using the Kaplan-Meier method for the time between the treatment and the patient's death.

Statistical Analysis

The chi-square test or Fisher's exact test and Student's t-test were utilized to determine the significance of the differences between groups. The survival rates were analyzed using Kaplan-Meier analysis and the log-rank test. Statistical significance was set at a P level < 0.05. Statistical analysis was performed using SPSS software, Version 16.0 (Chicago, USA).

Results

Patient Data

Sixty-eight patients received allocated intervention (Fig. 1): the filter group comprised 33 patients who received filter implantation (Fig. 2), and the control group comprised 35 patients who did not receive filter implantation (Fig. 3). Because of the loss of contact with patients and