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ORIGINAL ARTICLE

Development and evaluation of a new biodegradable vena cava filter in a canine model

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Summary *Purpose:* Preliminary testing of a new biodegradable inferior vena cava filter in a canine model.
Methods: The biodegradable filter consisted of two parts, a filter cone and a stent. The filter cone was constructed of six polyglycolic acid polymer strands anchored to a handmade absorbable stent. Central inferior vena cava fixation was accomplished by the absorbable stent, which was made of polycaprolactone. Device insertion was performed through a 9F sheath under ultrasound guidance on 10 adult beagles. The filters were operatively retrieved at 6 weeks after implantation. The inferior venae cavae were subsequently analyzed grossly and using light microscopy.
Results: None of the 10 beagles had abnormal vital signs. All of the 10 filters migrated cephalad approximately <2 cm and remained below the renal vein ostia. One specimen had evidence of incorporated residual strands within the caval wall on gross examination. The caval wall became thickened at the level of filter placement without significant lumen narrowing. There was no evidence of pulmonary embolism caused by degradation products of the absorbable strands.
Conclusion: Biodegradable inferior vena cava filters are feasible and potentially could be used in specific patients who are at temporary high risk of venous thromboembolism.

Conflicts of interest: All contributing authors declare no conflicts of interest.

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1. Introduction

Pulmonary embolism (PE) is a common and potentially lethal disease that causes approximately 200,000 deaths/y in the USA.[1] For almost one-quarter of PE patients, the initial clinical presentation is sudden death.[2] The vena cava filter (VCF) is designed to prevent fatal PE by capturing any large emboli from the legs and pelvis. VCF placement has increased significantly since the Greenfield filter was introduced in 1973. The number of patients who have received VCF in the USA for the prevention of PE has increased from 2000 in 1979 to 49,000 in 1999, and there has been a threefold increase from 2001 to 2006.[3,4] The primary reason for this increase is the introduction of retrievable filters, which has expanded prophylactic use.

Despite the large number of VCFs used worldwide, there has been only one randomized trial on permanent filters. The PREPIC trial demonstrated the initial beneficial effect of vena caval filters for the prevention of PE was counterbalanced by an excess of recurrent deep-vein thrombosis (20.8% vs. 11.6%), without any difference in mortality.[5] After 8 years of follow up, the PREPIC trial data confirmed the early findings of reduced risk of PE but increased incidence of recurrent deep-vein thrombosis (35.7% vs. 27.5%).[6]

Retrievable VCFs theoretically can overcome the long-term complications associated with permanent filters; they offer protection against PE during the period of highest risk with the option of removal before becoming permanently incorporated into the vena cava. However, rates of attempted retrieval are low, primarily due to loss to follow up. Karmy-Jones et al[7] reported that only 22% of optional VCFs placed in 446 trauma patients were retrieved. A similar dismal removal rate of only 21% in >5000 patients studied was reported by Antevil et al.[8] Removal is invasive and may cause additional complications that increase hospital stay and cost.

The biodegradable VCF is an innovative concept. The biodegradable endovascular stent is a promising device that may replace traditional metallic stents for endovascular treatment. A recent study has demonstrated the efficacy, biocompatibility, and safety of fully biodegradable stents in human coronary arteries after >10 years' follow up.[9] Biodegradable polymers including poly-l-lactic acid, polyglycolic acid, poly(D,L-lactide/glycolide) copolymer, and polycaprolactone (PCL), as well as magnesium alloy, have been widely used to construct absorbable stents.[10,11] Enlightened by the biodegradable stent, we developed a new vena cava filter made totally of biodegradable material. It would provide the critical protection against PE at the period of the highest risk, while eliminating the long-term disadvantages of a permanent filter and avoiding the risks of a secondary procedure retrieving the filter.

The purpose of this study was to evaluate the feasibility, safety, and complications of a new biodegradable filter in a canine model.

2. Materials and methods

2.1. Filter design

The biodegradable filter consisted of two parts, a filter cone and a stent (Figure 1). The filter cone was constructed of six polyglycolic acid polymer strands anchored to an absorbable stent. The conical filter design made it possible to collect large thrombi while maintaining the maximum cross-sectional area for blood flow. The absorbable stent, which was made of PCL, anchored the filter to the vena cava after deployment. The diameter of the PCL strand we used was 1.0 mm. The PCL strand was bent consecutively by forceps to form 12 1.5-cm long struts of a Z-stent. Two Z frameworks were connected vertically using 4-0 Monocryl suture (Ethicon Inc., Somerville, NJ, USA) to construct a stent. The length of the stent was 2.5 cm, and diameter was 18 mm on full expansion. Six polyglycolic acid strands (Vicryl 3-0; Ethicon Inc.) were attached to the stent using six knots at each fixation point (Figure 2). The height

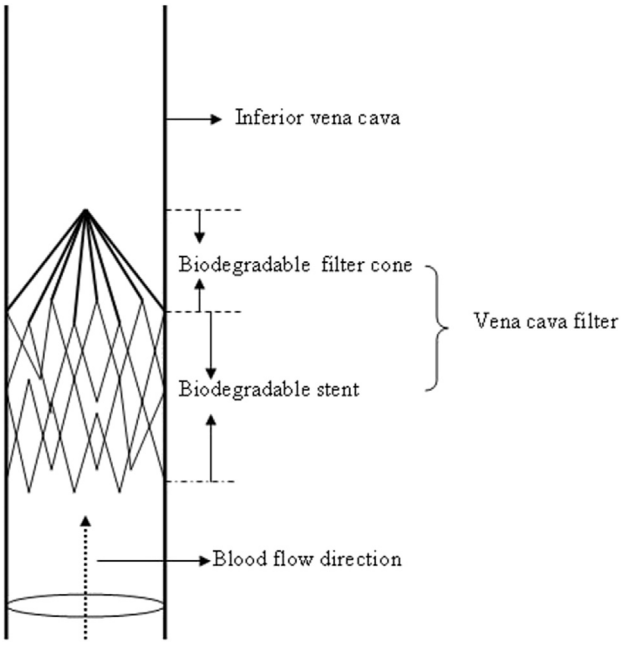

Figure 1 Schematic drawing of the biodegradable vena cava filter deployed in the vena cava. It consists of two parts, a filter cone and a stent. The filter cone is constructed of six polyglycolic acid polymer strands anchored to an absorbable stent. The absorbable stent, made of polycaprolactone, attaches the filter to the vena cava after deployment.

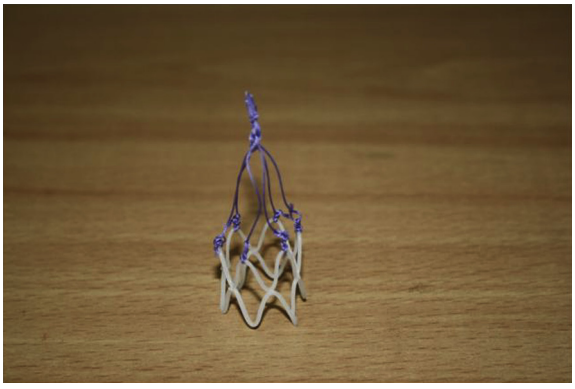

Figure 2 Our handmade biodegradable vena cava filter for implantation in canine vena cava.