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Systematic Review of Efficacy and Safety of Retrievable Inferior Vena Caval Filters

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Disclosures

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Introduction

Inferior vena caval (IVC) filters are used with the premise of preventing pulmonary embolism (PE). Concerns for complications due to longstanding dwell time led to development of retrievable filters, which were cleared by the Food and Drug Administration (FDA) in early 2000's. This temporally correlated with permissive recommendations for use in several clinical scenarios¹ and frequent utilization of IVC filters. Among Medicare Fee-For-Service beneficiaries with PE, one in every 6 received an IVC filter.²

Yet, overall evidence for efficacy of IVC filters remains limited.^{3,4} Further, some retrievable filters possess distinct features that may impact their efficacy and safety. At one hand, such features are presumably advantageous making them amenable to removal (e.g. when a patient no longer has contraindication to anticoagulation). However, alternative anchoring mechanisms may make these filters susceptible to tilting (with potential to reduce retrievability, but also to reduce efficacy), migration, perforation, and injury to adjacent organs.^{5,6} We performed a systematic review of the prospective controlled studies to determine the efficacy and safety of retrievable IVC filters.

Methods

We searched PubMed, the Cochrane Central Register of Controlled Trials and clinicaltrials.gov to identify controlled trials or prospective observational studies comparing the use of retrievable IVC filters versus control (last search: 9/8/2017). Main outcomes included PE, PE-related mortality, all-cause mortality, deep vein thrombosis (DVT), and bleeding.

Data were pooled using inverse variance fixed-effects models. We reported the risk ratio (RR) and 95% confidence interval (CI) for outcomes. We used the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) tool for assessment of the risk of bias and methodological quality for the studied outcomes within the included controlled trials. We used RevMan version 5.3 (The Nordic Cochrane Center, Copenhagen, Denmark) for analyses.

Results

We reviewed 2,058 citations and identified 3 relevant trials,^{7–9} and 4 prospective controlled observational cohorts where at least some patients received retrievable filters. For 3 observational studies, the data were unavailable. We received the relevant subgroup data from the other study.¹⁰

Pooled results (total of 852 patients) did not indicate a significant change in the rate of subsequent PE (RR: 0.81; 95% CI: 0.32–2.07) or PE-related mortality (RR: 1.75, 95% CI: 0.50–6.12, Figure 1). No significant difference was observed in the rate of all-cause mortality (RR: 1.01, 95% CI: 0.62, 1.64), subsequent DVT (RR: 1.56, 95% CI: 0.46, 5.30, Figure 2), or bleeding (RR: 0.78, 95% CI: 0.42, 1.44). Findings were similar when risk difference was used as the effect measure. According to the GRADE criteria, there were no serious limitations for risk of bias for the studied outcomes, however, there were serious

limitations for directness and precision, owing to heterogeneity of studied populations and small number of enrollees.

Discussion

Only a handful of prospective controlled studies related to retrievable IVC filters exist with a total of 852 patients, affirming the dearth of evidence for a relatively common procedure. Our results did not show a significant difference in the rates of PE, PE-related mortality, or all-cause mortality in those receiving retrievable IVC filters versus controls.

We urge caution in interpretation of our findings. Our study does not prove the lack of efficacy of retrievable IVC filters. In certain situations, clinicians may opt to consider them. However, our study indicates the finite evidence base for this device sub-class. Such available evidence is partially different from the overall (still limited) evidence for IVC filters as a class of device. Contrary to our prior study,⁴ for retrievable filters we did not observe increased risk of DVT, but also no significant reduction in the rate of subsequent PE or PE-related mortality (numeric increase for the latter).

This study is limited by the clinical heterogeneity (i.e. various indications) and small number of patients (<1,000), limiting the power. In addition, an alternative way of assessment of the efficacy and safety of retrievable filters is to randomize patients to “IVC filter insertion and retrieval” versus control. To our knowledge, however, such a study—which is difficult to conduct—has not been conducted yet. Our results provide further impetus for investigators, manufacturers, and the FDA to help improve the evidence base for IVC filters. Further, we initially planned to investigate complications such as tilting, IVC perforation, and injury to the neighboring organs but were unable because of concerns for inconsistent or under-reporting across studies.⁶ The ongoing Predicting the Safety and Effectiveness of Inferior Vena Cava Filters study would shed further light on the safety of these filters.

In conclusion, insufficient data exist on the efficacy of retrievable IVC filters, in addition to safety concerns addressed elsewhere.⁶ Prospective controlled studies are required to ascertain the efficacy, and population-based prospective studies to characterize the safety of these devices.

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Figure 1.
Subsequent PE (A) and PE-related Mortality (B)

Figure 2.
Subsequent All-cause Death (A) and DVT (B)