subjects with type 2 diabetes status, whereas no exercise was superior to resistance and combined exercise for improving mental health status. The authors claimed insufficient statistical power and/or the effect of fatigue to explain the lack of improvement in the physical component summary measures with mixed training and attributed to a “reversion to the mean” phenomenon the improvement in the mental component summary measures in the control group, starting with a lower mean score at baseline than the exercise intervention groups.

A possible limitation of this study, in addition to intrinsic limitation of the SF-36 survey, is the unblinded design, though blinding is not feasible in clinical trials using behavioral interventions. Strengths of this study are that it was multicenter, thus less dependent on local factors, and of larger size and longer duration than other exercise intervention trials in patients with type 2 diabetes, including those assessing QoL and well-being measures.2–4

In conclusion, this large trial shows that the health benefits induced by supervised mixed exercise training on top of counseling include a significant improvement in physical and mental health-related QoL measures. Thus, this intervention strategy may be effective for promoting permanent lifestyle changes in subjects with sedentary habits, such as patients with type 2 diabetes.

Antonio Nicolucci, MD
Stefano Balducci, MD
Patrizia Cardelli, PhD
Silvano Zanuso, PhD
Giuseppe Pugliese, MD, PhD
for the Italian Diabetes Exercise Study (IDES) Investigators

Author Affiliations: Department of Clinical Pharmacology and Epidemiology, Consorzio Mario Negri Sud, S. Maria Imbaro, Chieti, Italy (Dr Nicolucci); Metabolic Fitness Association, Monterotondo, Rome, Italy (Dr Balducci); Department of Clinical and Molecular Medicine, “La Sapienza” University, and Diabetes Division (Drs Balducci and Pugliese) and Laboratory of Clinical Chemistry (Dr Cardelli), Sant’Andrea Hospital, Rome, Italy; and School of Science, University of Greenwich, London, England (Dr Zanuso).

Group Information: A complete list of the IDES Investigators is given in the eAppendix.

Correspondence: Dr Pugliese, Department of Clinical an Molecular Medicine, “La Sapienza” University of Rome, Via di Grottarossa, 1035-1039, 00189 Rome, Italy (giuseppe.pugliese@uniroma1.it).

At the end of letter

Additional Contributions: Stefano Cavallo, MD, Sara Fallucca, PhD, Alessandra Bazuro, MD, Paola Simonelli, MD, and Carla Iacobini, PhD, from the Department of Clinical and Molecular Medicine, “La Sapienza” University, Rome, Italy, participated in the acquisition of data and critical revision of the manuscript.


Retrieval of Inferior Vena Cava Filters After Prolonged Indwelling Time

Pulmonary embolus (PE) remains the leading cause of preventable mortality in surgical patients and the third leading cause of death in hospitalized trauma patients.1 This has contributed to the 4-fold rise in use of inferior vena cava (IVC) filters following Food and Drug Administration approval of the first retrievable (or optional) IVC filter in 2003.2

See Invited Commentary at end of letter

Although IVC filters are efficient at preventing PE, they may be associated with an increased risk of venous throm-
basis and other complications. Filter retrieval rates remain less than 50%, with many reports citing an incidence less than 15%. Some reasons for failure of retrieval are related to prolonged indwelling time with associated potential for complications and medical comorbidities, which may also increase the risk of the procedure and/or increase mortality in cases of subsequent PE. We summarize our experience with successful filter retrieval after a prolonged indwelling time and also to describe barriers encountered in removing filters.

Methods. After obtaining institutional review board approval, a retrospective study was performed on all IVC filters inserted from January 2004 to July 2009 and from January 2010 to June 2011. A dedicated database and advanced practitioner were used to track patients and assess feasibility of filter removal.

We tracked several retrievable filters; the G2 filter (Bard Peripheral Vascular), which is recommended for removal up to 300 days, the Gunther Tulip filter (Cook Medical), which is recommended for removal up to 20 days, and the Celect filter (Cook Medical), which is approved for removal up to 469 days following insertion.

Results. A total of 289 consecutive patients underwent IVC filter placement, 19 of whom were lost to follow-up. Filters placed included 211 G2 filters, 57 Gunther Tulip filters, and 2 Celect filters. The mean (SD) patient age was 51 (21) years, and follow-up time was 2.3 years (range, 70 days to 5.8 years). From 2004 to 2009, IVC filter retrieval was attempted in 97 patients and successfully completed in 90 (33%). The number of filters placed increased from January 2010 to June 2011 but the retrieval rate remained only 22%.

The most common reason for IVC filter placement was prophylaxis in patients with significant risk factors for venous thromboembolic disease (VTED). The most common reasons for not removing a filter were related to prolonged indwelling time with associated potential for complications and medical comorbidities, which may also increase the risk of the procedure and/or increase mortality in cases of subsequent PE. We summarize our experience with successful filter retrieval after a prolonged indwelling time and also to describe barriers encountered in removing filters.

Table. Reasons IVC Filter Retrieval Was Not Attempted

<table>
<thead>
<tr>
<th>Reason</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician refused</td>
<td>37 (21)</td>
</tr>
<tr>
<td>Unable to anticoagulate</td>
<td>33 (18)</td>
</tr>
<tr>
<td>Age &gt;70 y</td>
<td>28 (16)</td>
</tr>
<tr>
<td>Deceased</td>
<td>27 (15)</td>
</tr>
<tr>
<td>VTED on anticoagulation</td>
<td>5 (3)</td>
</tr>
<tr>
<td>Prolonged immobility</td>
<td>13 (7)</td>
</tr>
<tr>
<td>Terminal disease</td>
<td>7 (4)</td>
</tr>
<tr>
<td>Failed retrieval</td>
<td>7 (4)</td>
</tr>
<tr>
<td>Pending retrieval</td>
<td>11 (6)</td>
</tr>
<tr>
<td>Pending operation</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Clot in filter</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Unknown</td>
<td>10 (6)</td>
</tr>
</tbody>
</table>

Abbreviations: IVC, inferior vena cava; VTED, venous thromboembolic disease.

Comment. The incidence of IVC filter insertion has increased dramatically since the FDA first approved the placement of retrievable (or optional) IVC filters in 2003. Despite reports of complications related to prolonged indwelling of IVC filters, retrieval rates remain well below 50% in most reports.

Our study found that IVC filters can be removed safely following prolonged indwelling times but also confirmed the low overall retrieval rate. The most common reason for not attempting retrieval was physician refusal. This is particularly striking given that 54% of filters were placed for prophylactic reasons. Furthermore, the reason cited for not removing the filter in an additional 18% of patients was inability to anticoagulate. However, the 2008 American College of Chest Physician guidelines specifically recommend that IVC filters be removed 6 months following a pulmonary embolus irrespective of the ability to anticoagulate the patient. Retrieval rate was not changed following publication of these guidelines.

In conclusion, retrieval rates of IVC filters remain low despite guidelines urging timely removal to mitigate filter-related complications. Educational efforts regarding the importance and safety of filter removal should be directed to physicians who refer patients for IVC filter placement, and future studies evaluating the efficacy of this approach in improving IVC filter removal rates are needed.

Franklin Garcia-Godoy, DO
Tara Collins, CRNP
David Sacks, MD
Steve Vasas, PA-C
Babak Sarani, MD

Author Affiliations: Department of Surgery, Philadelphia College of Osteopathic Medicine, Philadelphia, Pennsylvania (Dr Garcia-Godoy); Department of Nursing, Hospital of the University of Pennsylvania, Philadelphia (Ms
Collins); Advanced Interventional Radiology, The Reading Hospital and Medical Center, West Reading, Pennsylvania (Dr Sacks and Mr Vasas); and Division of Traumatology, Surgical Critical Care, and Emergency Surgery, University of Pennsylvania, Philadelphia (Dr Sarani).

Correspondence: Dr Sarani, Department of Surgery, University of Pennsylvania, 3400 Spruce St, 5 Maloney, Philadelphia, PA 19104 (saranii@uphs.upenn.edu).

Author Contributions: Study concept and design: Garcia-Godoy, Collins, Sacks, and Sarani. Acquisition of data: Collins, Sacks, and Vasas. Analysis and interpretation of data: Garcia-Godoy, Sacks, and Sarani. Drafting of the manuscript: Garcia-Godoy, Collins, and Sarani. Critical revision of the manuscript for important intellectual content: Garcia-Godoy, Sacks, Vasas, and Sarani. Administrative, technical, and material support: Garcia-Godoy, Collins, Vasas, and Sarani. Study supervision: Sacks and Sarani.

Financial Disclosure: None reported.


INVITED COMMENTARY

Efforts to Optimize Patient Benefit From Inferior Vena Cava Filters

Theoretically, retrievable inferior vena cava (IVC) filters offer the advantage of prevention of pulmonary embolism (PE) without the associated risks of long-term permanent devices. Confidence in the efficacy and safety of retrievable IVC filters has led to a doubling in the placement of these devices over the past decade.1 However, Medicare database analysis showed that of the 65,041 devices placed in 2008, only an estimated 15% were retrieved.1 As these devices may be associated with significant complications, which increase over time, including a high risk of future deep vein thrombosis (DVT) and IVC thrombosis, all efforts should be made to avoid unnecessary long indwelling time. The US Food and Drug Administration (FDA) released a statement in August 2010 urging clinicians to remove these devices as soon as the risk of PE has subsided. This was based on finding nearly 1000 reported complications associated with these devices, a review prompted by an article published in the Archives that described an alarmingly high filter fracture rate with certain devices.2,3

Barriers to IVC filter retrieval include physician refusal, perhaps due to lack of appreciation for consequences of permanent devices, ongoing contraindication to anticoagulation, long indwelling time, and loss of patients to follow-up. To decrease the number of IVC filters that are left in place permanently, we should first help educate clinicians to identify appropriate candidates for placement. Recent studies suggest that only half of all IVC filter placements were appropriate per professional society guidelines.4 Next, a system should be in place to track the fate of the device. Leaving this up to the patient or primary care physician is not acceptable. Institution of an IVC filter clinic has been shown to result in a 2-fold increase in retrieval rates.5 A weekly multidisciplinary review of filter placement request and indication, repositioning, and retrieval resulted in an 80% reduction in retained devices without an absolute indication.6 Mandatory postmarketing registries would provide a way to assess safety and efficacy of various devices and could provide valuable information on both complication retrieval rates.

In this issue of the Archives, Godoy-Garcia and colleagues7 advance this field further with their report of their experience with removal of IVC filters after a prolonged indwelling time. In their cohort, the most common indication for placement was prevention of venous thromboembolism (VTE) when pharmacologic prophylaxis was contraindicated (53%), followed by VTE despite anticoagulation (31%) and contraindications to anticoagulation secondary to bleeding complications in patients with known VTE (9%).

While the only available randomized control trial evaluating IVC filter efficacy shows a reduction in both short- and long-term recurrence of PE in patients with acute DVT, these patients all received anticoagulation and therefore were not representative of the patients who most commonly receive these devices.8,9 There is currently no high-level data to support the most common use of IVC filters, that is prevention of VTE in patients who are not on anticoagulation.

IVC Filter Placement. The controversy surrounding patient selection for IVC filter placement is reflected in the disparate recommendations found in guidelines from various sources (Table). The only currently agreed-on indication for IVC filter placement is prevention of PE in the setting of DVT and a contraindication to anticoagulation. Other indications remain controversial. While filters were once commonly placed in patients who developed recurrent or progressive DVT or PE despite anticoagulation, now most experts recommend an increase in intensity of anticoagulation or initiation of an alternative anticoagulant rather than placement of a device. Despite practitioners’ concerns, free-floating thrombus...