Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade

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Background: Vena cava filters represent an alternative treatment option for patients with contraindications to anticoagulation, or they might serve as adjunctive treatment for continued emboli despite anticoagulation. The fracture of a filter strut with subsequent end-organ embolization is a rarely reported but potentially life-threatening occurrence.

Methods: We sought to determine the prevalence of fracture and embolization of the Bard Recovery (first generation) and the Bard G2 (second generation) vena cava filters. A retrospective, single-center, cross-sectional study was conducted by evaluating all patients who received either a Bard Recovery or Bard G2 filter from April 2004 until January 2009. A total of 189 patients had undergone implantation: 1 pregnant woman and 35 patients who died were excluded from our study. In addition, 10 patients who had the filter removed were also excluded. Ultimately, 80 patients participated in the trial. Subjects underwent fluoroscopy to assess the filter’s integrity. Embolized struts were localized by fluoroscopy. Echocardiography and cardiac computed tomography were performed in patients with fragment embolization to the heart.

Results: Thirteen of 80 patients had at least 1 strut fracture (16%). At least 1 strut in 7 of the 28 Bard Recovery filters fractured and embolized (25%). In 5 of these 7 cases, patients had at least 1 fragment embolize to the heart (71%). Three patients experienced life-threatening symptoms of ventricular tachycardia and/or tamponade, including 1 patient who experienced sudden death at home. Six of 52 Bard G2 filters fractured (12%). In 2 of these 6 cases, the patients had asymptomatic end-organ fragment embolization.

Conclusion: The Bard Recovery and Bard G2 filters had high prevalences of fracture and embolization, with potentially life-threatening sequelae.


See Invited Commentary at end of article

Venous thromboembolism occurs in more than 200,000 US citizens per year.1 Anticoagulation is the standard therapy for these patients. Vena cava filters have been used as an alternative therapy for patients who have contraindications to anticoagulation or as adjunctive treatment in patients with continued emboli despite anticoagulation.
the fractured fragments and drainage of the pericardial effusion.

In September 2005, Bard modified the design of the Bard Recovery filter to improve fracture resistance by reducing stress concentration at the apex of the filter using longer arms with curved ends to reduce the load to the arms as they exit the apex. This new design was labeled and marketed as the Bard G2 cava filter, replacing the initial Bard Recovery filter. Over 65,000 Bard G2 filters have been implanted since September 2005.

Based on our institution’s herald case and the limited case reports in the literature, we undertook a retrospective review of all patients at our institution who received the Bard Recovery filter or Bard G2 filter.

## METHODS

The institutional review board approved this study. Retrospective review of the procedure logs was used to identify all patients who received a Bard Recovery or Bard G2 filter from April 2004 until January 2009. We attempted to contact all nonpregnant living patients at their last known places of residence. Patients were asked to submit to fluoroscopy of the filter to assess its integrity. If a device had fragmented, all embolized nitinol arms or legs were localized on fluoroscopy, and their locations were recorded. Transthoracic echocardiography was performed in all patients who had fragment embolization to the heart. Selected patients with embolization to the heart also underwent cardiac computed tomography to further define the exact location of the fragments.

A total of 189 patients underwent implantation of the Bard Recovery or Bard G2 vena cava filter at our institution between 2004 and 2009, usually as treatment for deep-vein thrombosis or pulmonary embolus (Table 1). Because the Bard Recovery filter was first on the market and was later replaced by the Bard G2, the duration of time between filter implantation and fluoroscopy for the Bard G2 filter is shorter than that of the Bard Recovery filter.

Thirty-five of the 189 patients with Bard filters had died by the time of the study; 10 others had undergone routine scheduled prophylactic recovery of their filter; and 1 was pregnant and could not undergo fluoroscopy. Attempts were made to contact the remaining 143 patients by letter and telephone, and 84 patients were contacted, of whom 80 agreed to participate in the trial. After informed consent, all 80 patients underwent fluoroscopy of the device. The patient enrollment flowchart is shown in Figure 2. Thirteen of the 80 patients who underwent fluoroscopy were found to have at least 1 nitinol arm or leg fracture (16%). The average age for

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Complications subsequent to the initial placement of vena cava filters are multiple, and some occur with significant frequency. It is reported that up to 5% of all filters migrate further than 1 cm, with almost all occurrences being asymptomatic. Perforation or erosion of the filter through the vena cava at the site of implantation is more common but is usually without clinical consequence. Fracture of a filter strut has been reported rarely in the literature but has resulted in life-threatening events. In 2 of the cases found in the literature, the fractured filter fragment embolized to the heart and perforated the right ventricle. In 1 case, the patient had chest pain, and in the second case, the patient had life-threatening cardiac tamponade. Both patients underwent successful emergency open-heart surgery for removal of the fractured filter fragment. The Bard Recovery filter was the implanted device implicated in both of these cases. Hull and Robertson reported a third patient who had chest pain and nonsustained ventricular tachycardia necessitating removal of fragments from the heart and recovery of the remaining Bard Recovery filter from the vena cava.

Our retrospective review of patients receiving either the Bard Recovery filter or the Bard G2 filter demonstrates a high prevalence of fracture of these devices. The Bard Recovery filter had an overall fracture prevalence of 25% (7 of 28). Six of these 7 patients had at least 1 fragment embolize to the heart or beyond to the lungs (86%) (Figure 1), and 3 of the 7 patients experienced lifethreatening symptoms. While the Bard G2 filter incorporated engineering modifications to reduce these occurrences, 12% of the implanted Bard G2 filters also fractured (6 of 52). The modifications might have reduced the ability of the fragments to distally embolize—two-thirds of the fragments remained locally within the IVC near the original implantation site—but as demonstrated in patients 10 and 13, the potential for embolization out of the IVC to other vital organs still exists.

The observed prevalence of filter fracture was 25% with the Bard Recovery filter (7 of 28) and 12% in the Bard G2 filter (6 of 52). These data initially suggest that the fracture rate for the Bard G2 filter is approximately half that of the Bard Recovery filter. However, on further analysis, this conclusion may not be accurate. The average time between filter implantation and assessment of filter integrity for the Bard Recovery filter was 1498 days, or approximately 50 months. For the Bard G2 filter, the average time interval was 717 days, or approximately 24 months. The average time intervals in patients where fracture was observed in the Bard Recovery and Bard G2 groups were nearly identical to those of all patients in those respective groups.

Because nitinol metal fatigue may play a role in the filter fracture, it is reasonable to assume that the incidence of filter fracture would be directly proportional to the time that the filter is allowed to dwell in the patient after implantation. Lynch and Kekulawela reported their experience in removing Bard G2 filters before and after 180 days following implantation. A total of 3.4% of the filters removed had fractured prior to removal, and all fractures were observed in patients who had had the filter implanted for more than 180 days. Cantwell et al reported a lower observed prevalence of fracture than we observed of the Bard Recovery and Bard G2 filters on removal of the devices, but 95% of the filters in that study were recovered within 15.5 months of implantation.
The low rate of recovery in our study is similar to that reported for pulmonary embolism prophylaxis. Although the recovery period for patients with the Bard Recovery filter without complications is on average 899 days, patients with the Bard G2 filter who had filter fracture, migration, and perforation were left in place, owing to potential long-term indications without filter fragmentation. Many of the implanted devices were therefore experiencing prolonged exposure to repetitive movement and subsequent metal fatigue, potentially predisposing them to fail. We would contend that the fracture prevalence seen by Cantwell et al.8 might have been significantly higher if the filter (which has a permanent implant indication) was allowed to remain in place for a longer period. If one were to extrapolate our observed prevalence of Bard G2 filter fractures to 50 months (essentially double the observed period), the prevalence of fracture would be identical to that observed for the Bard Recovery filter, thus challenging the hypothesis that the Bard G2 filter represents an improvement in fracture resistance.

Table 2. Characteristics of the 13 Patients Found on Fluoroscopy to Have Filter Fragmentation

<table>
<thead>
<tr>
<th>Patient No./Age, y</th>
<th>Bard Filter Devicea</th>
<th>Indication for Implantation</th>
<th>Duration of Implantation, mo</th>
<th>Implanting Physician-No.</th>
<th>No. of Fractured Fragments: No. in Embolization Location</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/78</td>
<td>Recovery</td>
<td>Pulmonary emboli</td>
<td>56</td>
<td>IR-1</td>
<td>3 arms: 2 heart, 1 lung</td>
<td>Palpitations, VPCs and couplets, CP, SOB</td>
</tr>
<tr>
<td>2/54</td>
<td>Recovery</td>
<td>Surgery prophylaxis</td>
<td>37</td>
<td>GS-1</td>
<td>3 arms: 3 heart</td>
<td>CP, SOB, tamponade</td>
</tr>
<tr>
<td>3/48</td>
<td>Recovery</td>
<td>Surgery prophylaxis</td>
<td>52</td>
<td>GS-2</td>
<td>1 arm: 1 liver</td>
<td>None</td>
</tr>
<tr>
<td>4/73</td>
<td>Recovery</td>
<td>Surgery prophylaxis</td>
<td>52</td>
<td>GS-2</td>
<td>2 arms: 1 in each lung</td>
<td>SOB</td>
</tr>
<tr>
<td>5/27</td>
<td>Recovery</td>
<td>Malignant neoplasm prophylaxis</td>
<td>51</td>
<td>GS-2</td>
<td>3 arms: 2 heart, 1 lung</td>
<td>None</td>
</tr>
<tr>
<td>6/26</td>
<td>Recovery</td>
<td>Trauma</td>
<td>52</td>
<td>IR-2</td>
<td>3 arms and 1 leg: 2 heart, 1 lung, 1 local in IVC</td>
<td>CP, SOB, NSVT</td>
</tr>
<tr>
<td>7/63</td>
<td>Recovery</td>
<td>Surgery prophylaxis</td>
<td>44</td>
<td>GS-3</td>
<td>1 arm: 1 heart</td>
<td>CP, NSVT, sudden death</td>
</tr>
<tr>
<td>8/21</td>
<td>G2</td>
<td>Trauma</td>
<td>35</td>
<td>VS-1</td>
<td>1 leg: 1 local in IVC</td>
<td>None</td>
</tr>
<tr>
<td>9/37</td>
<td>G2</td>
<td>Surgery prophylaxis</td>
<td>29</td>
<td>GS-2</td>
<td>1 leg: 1 local in IVC</td>
<td>None</td>
</tr>
<tr>
<td>10/75</td>
<td>G2</td>
<td>Pulmonary emboli</td>
<td>29</td>
<td>GS-2</td>
<td>1 arm: 1 liver</td>
<td>None</td>
</tr>
<tr>
<td>11/49</td>
<td>G2</td>
<td>Unknown</td>
<td>18</td>
<td>IR-2</td>
<td>2 legs and 1 arm: all local in IVC</td>
<td>None</td>
</tr>
<tr>
<td>12/30</td>
<td>G2</td>
<td>Trauma</td>
<td>10</td>
<td>GS-2</td>
<td>1 leg: 1 local in IVC</td>
<td>None</td>
</tr>
<tr>
<td>13/55</td>
<td>G2</td>
<td>Surgery prophylaxis</td>
<td>27</td>
<td>GS-2</td>
<td>1 arm: 1 lung</td>
<td>None</td>
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Abbreviations: CP, chest pain; GS, general surgeon; IR, interventional radiologist; IVC, inferior vena cava; NSVT, nonsustained ventricular tachycardia; SOB, shortness of breath; VPCs, ventricular premature contractions; VS, vascular surgeon.

*a“Recovery” and “G2” are proprietary names of vena cava filters manufactured by Bard Peripheral Vascular, Tempe, Arizona.

*bFour different physicians implanted filters, which went on to fracture, with 10 of these devices implanted by the same physician.

(mean, 7.5 months). There was a high prevalence of fracture in this short period with the Bard Recovery filter (9%) but no fractures of the Bard G2 filter. Our follow-up periods of 50 months for the Bard Recovery Filter and 24 months for the Bard G2 filter were much longer. These devices are therefore experiencing prolonged exposure to repetitive movement and subsequent metal fatigue, potentially predisposing them to fail.

We would contend that the fracture prevalence seen by Cantwell et al.8 might have been significantly higher if the filter (which has a permanent implant indication) was allowed to remain in place for a longer period. If one were to extrapolate our observed prevalence of Bard G2 filter fractures to 50 months (essentially double the observed period), the prevalence of fracture would be identical to that observed for the Bard Recovery filter, thus challenging the hypothesis that the Bard G2 filter represents an improvement in fracture resistance.

Of the filters that went on to fracture in our study, 6 different physicians from 3 different disciplines had implanted the devices. While it is possible that our findings may represent a local phenomenon, it is difficult to assert that fracture and fragmentation is an operator-dependent event.

The results of this study point to a difficult clinical challenge to the treating physician advising patients with and without filter fragmentation. Many of the implanted devices are left in place, owing to potential long-term indications for pulmonary embolism prophylaxis. Although the recoverable nature of the filter allows for recovery at a later date, the low rate of recovery in our study is similar to that reported in other series.8 As such, the ability to safely remove the device after it experiences local fibrosis into the vena cava may be compromised. It is encouraging that Hull and Robertson8 reported 100% successful retrieval of the Bard Recovery filter without complications an average of 899 days after initial implantation in patients requesting Bard Recovery filter removal (12 of 12). In addition, Lynch and Kekulawela reported a similarly large-volume experience with safe late removal (>180 days after implantation) of the Bard G2 filter.

The fact that fragment removal from the heart obviously requires open-heart surgery also poses a difficult clinical decision for a physician caring for a patient who has had embolization of fragments to the heart. While echocardiography is useful to determine if a pericardial effusion is present in these patients, absence of effusion at evaluation does not exclude the possibility of its later development or the occurrence of ventricular tachycardia.

Thirty-five of the 189 patients who underwent vena cava filter implantation at our center had died by the time of this study (19%). Indication for filter implantation obviously selects a patient population with a high mortality rate. Twenty-four of the 35 dead patients in our overall population (69%) died either during the hospital stay when the filter was implanted or within 6 months after the implantation.

Reported filter fractures and migration are rare, and it is not a well-known potential clinical complication. Therefore, the clinical suspicion of a filter fracture and migration being the cause of a patient’s complaints or symptoms will be low. Patients with perforation of the right heart and tamponade may have shortness of breath, pleuritic chest discomfort, dizziness, and syncope. Death might also result. These are the same symptoms found in patients with pulmonary emboli. One could hypothesize that some patients who might subsequently be seen with presumed symptoms of recurrent pulmonary emboli may in fact have had filter fracture, migration, and perforation.

It is essential that patients and their treating physicians be educated about this previously unrecognized and potentially life-threatening complication of these devices. Armed with this knowledge, educated patients can be alert to the presence of pleuritic chest pain and other symptoms that should prompt immediate evaluation. Such early awareness and evaluation could certainly be life saving. In addition, the propensity for filter fragmentation may be directly related to the duration of implantation. Patients and their physicians...
should be educated about this fact so that they have the opportunity to consider having the filter removed.

It is important to recognize that our data represent only a single-center experience. However, 6 different physicians from 3 different specialties implanted the devices that went on to fracture. While our medical center is representative of most large tertiary care hospitals, it is important that our data be corroborated with independent evaluation of implanted devices from other centers. In addition, other brands of IVC filters must be evaluated to determine if our findings are specific to the Bard devices or are a flaw of all such filters.

In conclusion, the prevalence of fragmentation and embolization was found to be high in both the Bard Recovery (25%, 7 of 28) and the Bard G2 (12%, 6 of 52) vena cava filters. Dissemination of these results has a clear benefit for the medical community. Further implantation of these particular devices has been halted at our institution. Educating the medical community and patients on the possibility of device fragmentation and embolization will lead to future patient protection. The optimal approach to the treatment of patients who have already received one of these devices is unclear. Filter fragmentation and embolization might be due to metal fatigue, and therefore its incidence might be directly related to the time that it remains implanted. The decision whether to remove an implanted device will have to be tailored to each individual’s particular clinical scenario. It is essential that other medical centers evaluate patients who have received a Bard retrievable filter or any other IVC filter, both for patient safety and to corroborate our single-center findings.

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REFERENCES


HEALTH CARE REFORM

Medical Devices and the FDA Approval Process

Balancing Safety and Innovation

The use of medical devices has greatly increased during the past decade. Indeed, more than 8000 new medical devices are marketed in the United States annually. The US Food and Drug Administration (FDA) is responsible for assuring the safety and effectiveness of devices prior to and following approval for use in the United States. The FDA classifies medical devices according to risk of causing harm. Class I and II devices are considered to be low risk and approval may be accomplished through a relatively simple “premarket notification” or 510(k) clearance, which does not require clinical data. Class III devices are those consid-