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.

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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.

**RESULTS**

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 thrombus 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 flow-chart 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
this group was 48.9 years, and the device was evaluated, on average, 37.8 months after implantation (Table 2).

The subset of patients who had received the Bard Recovery filter had a 25% prevalence of device fragmentation and embolization (7 of 28). All Bard Recovery filter fractured fragments embolized via the venous system from the inferior vena cava (IVC) to an end organ. Five of the 7 fractured devices had at least 1 fragment embolize and come to rest in the right ventricle of the heart (71%). Two of these patients experienced symptoms of pleuritic chest pain with documented nonsustained ventricular tachycardia. Three months after completion of this study, 1 of these 2 patients experienced sudden death at home. Included in this group is the patient who experienced hemorrhagic pericardial effusion with subsequent cardiac tamponade requiring emergency open-heart surgery with drainage and fragment removal. In total, 6 of 7 patients who experienced fracture of a Bard Recovery filter (86%) had a fragment either embolize and come to rest in the right ventricle of the heart or continue moving within the venous system through the heart and into the pulmonary arteries. The 7 fractured Bard Recovery filters found on follow-up had been implanted by 3 different physicians, including an interventional radiologist and 2 different general surgeons.

The Bard G2 filter had a lower, but still high, fracture prevalence (12%; 6 of 52). Two of these 6 patients had a fragment embolize cephalad to the IVC, with 1 fragment coming to rest in the hepatic vein and 1 in the lung. Four of the 6 Bard G2 fragmented filters had the fractured strut(s) remain local to the original device implantation location in the IVC (67%). Three different physicians implanted the 6 filters that fragmented, including a vascular surgeon, an interventional radiologist, and a general surgeon.

**COMMENT**

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 we 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 life-threatening 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 Kekulawala 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.
vena cava may be compromised. It is encouraging that Hull move the device after it experiences local fibrosis into the reported in other series.9 As such, the ability to safely re-
date, the low rate of recovery in our study is similar to that
ations for pulmonary embolism prophylaxis. Although the
dvices are left in place, owing to potential long-term indi-
dents for the Bard Recovery filter, thus
ingredients may represent a local phenomenon, it is difficult to
elsewhere as to that observed for the Bard Recovery filter, thus
challenging the hypothesis that the Bard G2 filter rep-
resents an improvement in fracture resistance.

Of the filters that went on to fracture in our study, 6
different physicians from 3 different disciplines had im-
planted the devices. While it is possible that our find-
ings 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 chal-
lenge to the treating physician advising patients with and
without filter fragmentation. Many of the implanted de-
vices are left in place, owing to potential long-term indi-
cations 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.9 As such, the ability to safely re-
move the device after it experiences local fibrosis into the
vena cava may be compromised. It is encouraging that Hull
and Robertson6 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 Kekulawela7 reported a similarly large-volume expe-
rience with safe late removal (>180 days after implan-
tation) of the Bard G2 filter.

The fact that fragment removal from the heart obvi-
ously 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 echo-
cardiography is useful to determine if a pericardial effu-
sion is present in these patients, absence of effusion at eval-
uation 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 ob-
viously selects a patient population with a high mortality
rate. Twenty-four of the 35 dead patients in our over-
all 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. There-
fore, the clinical suspicion of a filter fracture and migra-
tion being the cause of a patient’s complaints or symp-
toms will be low. Patients with perforation of the right heart
tamponade may have shortness of breath, pleuritic chest
discomfort, dizziness, and syncope. Death might also re-
sult. These are the same symptoms found in patients with
pulmonary emboli. One could hypothesize that some pa-
tients 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 underrecognized and po-
tentially 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

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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>
</tr>
</tbody>
</table>

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.

69% reported a similarly large-volume experience with safe late removal (>180 days after implantation) of the Bard G2 filter.
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-
tered high risk; Class III devices generally require a premarket approval (PMA) process that includes clinical data showing safety and effectiveness. When Congress established device classes in 1976, its intent was that all Class III devices eventually would be required to undergo premarket review through the more stringent PMA process.2

Recently, the process for device approval has come under scrutiny owing to the poor quality of evidence supporting the PMAs on which devices have been approved and owing to the large percentage of high-risk devices that bypass PMAs altogether and are approved through 510(k) clearances.3,4 In particular, despite the surprisingly weak PMA data, a 2009 Government Accountability Office study discovered that the FDA did not deny approval of a single PMA submission between 2003 and 2007.2 Moreover, even though the FDA claims that “most Class III devices require Premarket Approval,” nearly 60% of the Class III devices approved during this period failed to undergo the PMA process at all and instead received 510(k) clearances which do not require clinical data.4 These statistics alone strongly suggest that the FDA’s device approval process needs urgent improvements.

In making approval decisions the FDA must protect the public safety without stifling innovation through unnecessary delays in approval. The Critical Path Initiative5 was launched in 2004 with the goal of shortening the time to approval for new drugs and devices by “developing better evaluation tools like biomarkers and new assays and streamlining clinical trials by modernizing the clinical trial sciences to make trials safe and efficient.” The FDA Center for Devices and Radiologic Health has established a Council on Medical Device Innovation. A recent public workshop6 (June 2010) brought together industry representatives, physicians, and patients and other members of the public in an effort designed, according to the Center Director, Jeffrey Shuren, to “get better devices to patients faster.”

Faster approval, however, increases the need for high-quality, reliable data showing safety and effectiveness to support approval. In addition, the collection of postapproval data becomes more crucial. This need for long-term follow-up is especially important for high-risk cardiovascular devices, which generally are permanently implanted in patients. However, the longest follow-up for high-risk cardiovascular devices approved via the more stringent PMA process was only a median of 365 days for intracardiac devices and endovascular grafts.3

In their study, Nicholson and colleagues report a serious and possibly fatal complication of the popular and widely used Bard inferior vena cava (IVC) filters (Bard Peripheral Vascular, Tempe, Arizona). Three years after receiving an IVC filter, one of the authors’ patients presented with pleuritic chest pain and cardiac tamponade as a result of filter fragmentation and embolization of the device. The group thereafter contacted all of their patients who had received Bard Recovery and Bard G2 filters to further investigate the longer-term effects. They found that the filters had fractured in an astounding 25% of patients implanted with the Bard Recovery filter (approved in 2002). For patients implanted with the newer Bard G2 filter (approved in 2005), they found fracturing in 12% of patients. They theorize that the lower rate for the newer filter is due to the shorter indwelling time and predict G2 filter fractures will rise over time. Extrapolating this data for the 65,000 G2 filters that have been implanted suggests that more than 7000 Americans may now be carrying a fractured G2 filter, with the potential to embolize to the IVC and beyond. Moreover, although the devices were approved as retrievable, the data suggest removal is not simple: less than 7% of devices were removed according to the article by Nicholson and colleagues. The safety of removal of the device after long-term use is not well established.

Remarkably, these filters, which are placed inside the IVC, were considered Class II by the FDA—the same risk category of mercury thermometers—and received approval without any clinical data of safety and effectiveness identified in their 510(k) clearances. The only performance data listed in the Bard Recovery Summary (K022236)7 describes bench testing performed per the FDA document “Guidance for Cardiovascular Intravascular Filter 510(k) Submission.” Testing showed that the Recovery filter is substantially equivalent to the Bard predicable device. The Bard Recovery Filter was submitted as a “Special 510K” pursuant to which a manufacturer may “declare conformance to design controls without providing the data.” In that case, the manufacturer need only submit a “Declaration of Conformity” with design control requirements. For the Bard Recovery Filter, the only clinical data provided were to support the safety of removing the device and thus a retrievable filter was approved in a subsequent 510(k).8 Similarly, the G2 filter Summary (K050558)9 has no clinical data, only a list of similarities to the Bard Recovery filter.

The report by Nicholson et al is a case study showing why the FDA device approval process must be more clearly defined. First, high-risk devices must go through the appropriate approval process adequately supported by reliable data. Manufacturers should not be routinely permitted to circumvent the PMA process for high-risk devices by means of 510(k) clearances. Second, PMAs must be supported by high-quality clinical data showing safety and effectiveness prior to approval of high-risk devices, including such products as valve rings, vascular filters, and other devices that are permanently implanted and can have serious adverse events, including death, after placement.

Fortunately, the FDA appears to be taking action. Among other things, the FDA has asked the Institute of Medicine to review the use of the 510(k) clearance, and a report with their recommendations is expected in spring 2011. In addition, in light of the fact that short-term studies often will miss less common problems, the process for developing and reviewing postmarket data must be significantly strengthened. Currently, required follow-up studies are often not completed, the follow-up data are not publicly available, and even if they are completed, the FDA rarely acts on the findings.

The FDA also has announced a new transparency initiative.10 Hopefully, this transparency will include requiring that clinical data submitted to the FDA, both in
the application process and postapproval, be publicly available. The FDA also must have authority and the will to withdraw device approvals if postmarketing data requirements are not met or if the postmarketing data show safety or effectiveness problems. Mechanisms for collecting postmarketing data must be made user friendly and publicly accessible. Registries such as the National Cardiovascular Data Registry and others are an important step in that direction. Currently, only 5% to 10% of all adverse events are actually reported. We have had many recent reminders that even those adverse events that are reported are not readily publicly available or turned over to the FDA in a timely fashion. The FDA recently sent another 12-page warning letter to Pfizer about delays in reporting adverse events dating back 6 years. The recent Avandia firestorm highlighted the importance of transparency of data. The problem is even more pressing and urgent for devices as seen in high-profile device recalls (Fidelis) as well as the recent Boston Scientific alert of serious problems with some of their implantable cardioverter-defibrillators.11

While we all appreciate the potential advantages of medical devices, prudent policy requires high-quality clinical data showing that the benefits outweigh the risks, before and after FDA approval. Holding manufacturers to these standards will enhance, not hinder, innovation and advancement of the science of medical devices.

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Editor

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