

Bard Denali Inferior Vena Cava Filter Fracture and Embolization Resulting in Cardiac Tamponade: A Device Failure Analysis

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ABSTRACT

A 46-year-old woman underwent inferior vena cava filter placement before bariatric surgery and returned within 6 months for routine removal. She complained of a 1-week history of severe chest pain, and during retrieval, two fractured filter components were identified including one arm in the right ventricle. The filter body and one fragment were successfully retrieved, but the fragment in the right ventricle was refractory to percutaneous retrieval. During open-heart surgery, the fragment was found traversing through the ventricular wall resulting in cardiac tamponade. Electron microscopic fragment analysis revealed high-cycle metal fatigue indicating the filter design failed to withstand this patient's natural inferior vena cava biomechanical motions.

ABBREVIATIONS

FDA = Food and Drug Administration, IVC = inferior vena cava, RV = right ventricle

The Bard Denali inferior vena cava (IVC) filter (C. R. Bard, Inc, Tempe, Arizona) was recently cleared by the U.S. Food and Drug Administration (FDA) based on interim trial data (1) showing no major complications. Although it is intended to be a new and improved Bard filter, the long-term safety and durability of this device remain unknown. We present the case of a life-threatening complication resulting from mechanical fatigue failure of the new Bard Denali IVC filter.

CASE REPORT

The patient was prospectively enrolled into an institutional review board–approved study registry. A 46-year-old woman with morbid obesity (body mass index, 58.88 kg/m²) complicated by diabetes mellitus, hyperlipidemia, hypertension, obstructive sleep apnea, asthma, low-back

pain, osteoarthritis, and depression was evaluated and scheduled for bariatric surgery. Although the patient had no history or family history of venous thromboembolic disease, IVC filter placement was desired before surgery for pulmonary embolism prophylaxis in the perioperative and postoperative period. During filter insertion, an IVC venogram showed a normal-caliber vena cava, and a Bard Denali IVC filter was deployed in the infrarenal IVC without complication. The patient underwent uneventful laparoscopic Roux-en-Y gastric bypass surgery 5 days later and was discharged on postoperative day 2. She missed her routine surgical follow-up appointments and did not initially respond when contacted for filter removal. Within 6 months (176 days) after filter insertion, the patient agreed to return and undergo filter removal. During evaluation before the procedure, she revealed new onset of severe chest pain radiating to her left shoulder. The chest pain had started 1 week earlier, and she admitted this was the reason she now returned to the hospital. Before the procedure, vital signs, electrocardiogram, serum cardiac enzyme assay, and chest radiograph were obtained urgently; all were normal. The chest x-ray showed clear lungs with no foreign bodies in the pulmonary circulation, but the plain film could not exclude a foreign body overlying the cardiac silhouette.

The patient was brought to the angiography suite. A spot fluoroscopic image was obtained over the abdomen, which showed embolization of one missing filter arm (Fig 1a, b) had already occurred centrally (Fig 2); a

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Figure E1 is available online at www.jvir.org.

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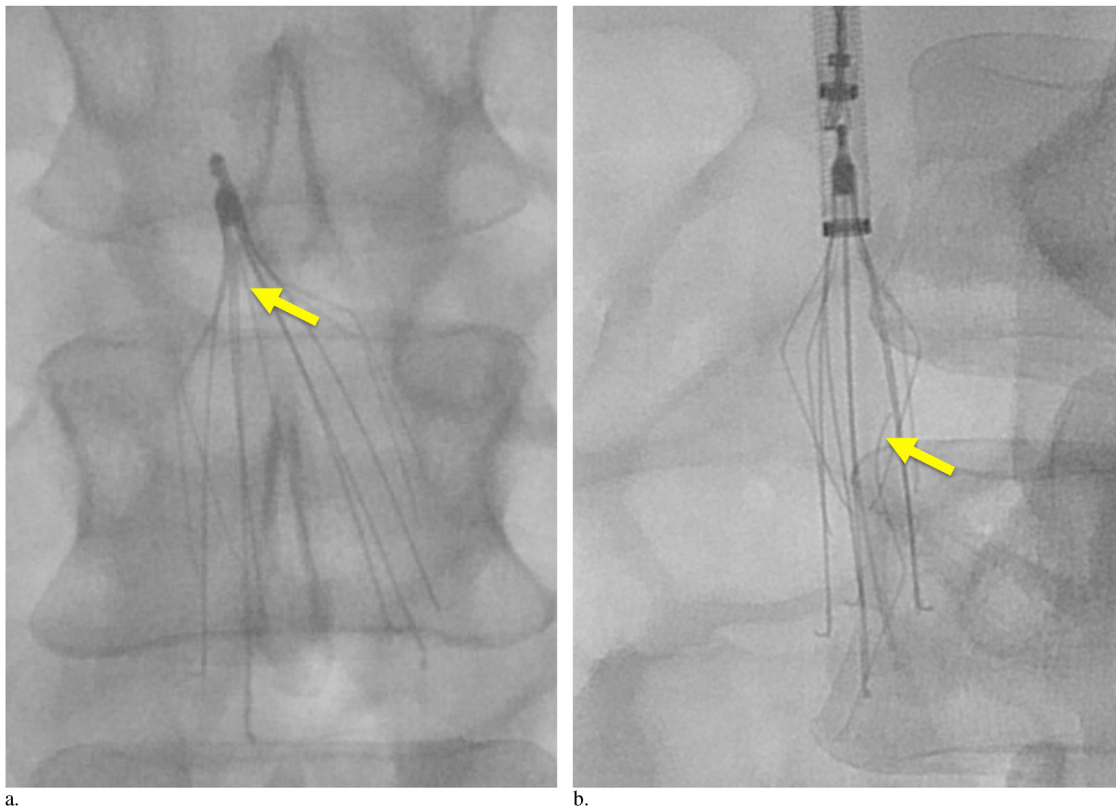


Figure 1. Spot fluoroscopic images (**a, b**) of the Bard Denali filter during retrieval. The term “arm” describes the shorter geometric components on the filter. Initial image (**a**) shows one missing fractured arm that was later identified within the right ventricle (see **Fig 2**); a second fractured arm (arrow) is seen disconnected from the apex. (**b**) After snaring of the filter apex, the second fractured arm (arrow) becomes more apparent. Embolization of this second arm into the left pulmonary artery would occur later (see **Fig 2**). (Available in color online at www.jvir.org.)

second fractured arm was also identified (**Fig 1b**). The right internal jugular vein was accessed, and a 12-F 45-cm sheath (Cook, Inc, Bloomington, Indiana) followed by an inner 9-F 55-cm sheath (Cook, Inc) were inserted over a guide wire into the IVC. An IVC venogram was obtained showing no caval thrombus and no obvious filter penetration. A 12- to 20-mm Ensnare (Merit Medical Systems, South Jordan, Utah) was inserted in an attempt to engage the filter hook; however, the hook was found to be embedded preventing snare engagement. Semirigid bronchoscopic forceps (Bryan Corporation, Woburn, Massachusetts) were inserted to dissect the embedded tip free using a previously described method (2). Next, the filter hook was snared, and the apex was sheathed. During this process, the second fractured arm became more apparent (**Fig 1b**). The main filter body was removed. Next, while we reinserted the forceps into the IVC, embolization of the free-floating filter arm into the left pulmonary artery occurred (**Fig 2**). The sheaths were exchanged for a 12-F 12-cm sheath (St. Jude Medical, St. Paul, Minnesota) and coaxial 8-F 40-cm Balkin sheath (Cook, Inc). The Ensnare was reinserted and formed in the left pulmonary artery. The free fragment was engaged and removed from the pulmonary artery. Next, a 6-F 45-cm Morph catheter (BioCardia, San Carlos, California)

was inserted and formed in the right ventricle (RV). The snare was inserted through the Morph and opened in the RV. Several attempts were made to engage the fragment in the RV while deflecting the snare loops toward the fragment using the Morph catheter, but no contact could be made with the fragment embedded in the RV, and the procedure was concluded.

The patient was admitted to the interventional radiology service for observation in a monitored bed, and the cardiothoracic surgery service was consulted. A chest computed tomography scan was performed, which showed the remaining filter fragment had traversed through the right ventricular wall resulting in cardiac tamponade (**Fig 3a, b**). The patient remained hemodynamically stable overnight, but she complained of persistent severe chest pain that was unchanged from 1 week prior. She was taken to the operating room the following morning and underwent a median sternotomy. A hemopericardium under tension was identified during pericardiectomy. After placing the patient on cardiopulmonary bypass, the right atrium was opened, and the RV was examined. The fractured filter arm was found traversing through the right ventricular wall. This fragment was carefully removed, and the wound in the RV was repaired. On postoperative day 5, a follow-up echocardiogram showed no significant abnormalities and no

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