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Bard Meridian Filter Fracture

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Disclosures

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Editor:

Fracture of an inferior vena cava (IVC) filter can result in strut migration and distant embolization of fractured limbs, leading to potentially serious health risks. Spontaneous limb fractures have been reported frequently with earlier models of retrievable Bard filters (Bard Peripheral Vascular, Tempe, Arizona), namely Recovery, G2, and G2X filters (1-4) but rarely reported in the newer Bard retrievable filter models. Recently, we encountered a case of

Meridian filter fracture discovered via computed tomography (CT) of the abdomen and pelvis one year after the filter placement procedure.

A 74-year-old woman with stage IV non-small cell lung cancer, osseous metastasis, and other comorbidities presented with acute hypoxia and hypotension. Acute and extensive pulmonary embolism involving bilateral lobar pulmonary arteries and distal branches was diagnosed after the patient underwent CT scanning. Ultrasound demonstrated evidence of venous thromboembolism (VTE) in the femoral vein. Because of the proximal VTE, an IVC filter was requested. A Bard Meridian filter was placed via the femoral approach in the infrarenal IVC at the L2-3 level with no complications.

The patient had multiple CT scans thereafter for cancer follow-up. A contrast-enhanced CT scan of the abdomen and pelvis (Fig 1) performed 368 days after the initial placement of the Meridian filter demonstrated fracture of a single arm (short limb) of the IVC filter, with cephalad migration of the fractured limb to approximately one cm superior to the filter apex in the IVC. The filter was otherwise well positioned without significant tilt or migration. No thrombus was present, and the patient was asymptomatic. Review of the CT scan of the abdomen performed at eight months after the procedure demonstrated no filter fracture, suggesting that the fracture occurred 8 to 12 months after the filter was placed. Although the interventional radiology service recommended retrieval of the fractured filter, this procedure was not performed because of the patient's desire for conservative management.

The Meridian filter is a fifth-generation Bard retrievable filter that was approved by the Food and Drug Administration (FDA) in 2011. The design of this filter was modified from that of the Eclipse filter, including the use of a new finish to improve fracture resistance and the addition of limb anchors to decrease the risk of filter migration. Despite these significant filter

design changes, there were no changes in the materials or manufacturing process used for Meridian filters. After encountering this case, we conducted a literature search and found a single case report of Meridian filter fracture with fragment migration to the heart (5). Further investigation into the FDA Manufacturer and User Facility Device Experience (MAUDE) database yielded 38 reported cases of spontaneous fractures involving the Meridian filter in 2013 alone; some of these fragments had distant embolization, including to the renal vein, pulmonary artery, right atrium, and right ventricle (6). The fracture potential of the Meridian filter, which is still on the market, therefore remains relevant now and in the future. The MAUDE database also included several reported cases of fractures involving the Eclipse filter, which is also still on the market. The manufacturer attempted to address these fracture concerns through the use of completely different materials and single piece laser-cutting technology with the latest Bard Denali filter, which was released in June 2013.

Although there are few data on the newer generations of IVC filters in the literature, healthcare providers and interventionalist in particular need to remain cognisant of the potential risks of device failure.

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Figure 1. Sagittal maximum intensity projection (MIP) CT image at one-year follow-up demonstrates fracture of a single limb of a Meridian IVC filter (white arrow) with cephalad strut migration of approximately 1 cm in the IVC.



184x250mm (96 x 96 DPI)