Certain vena cava filters may fracture, causing potentially life-threatening complications

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Two specific types of vena cava filters, devices used to prevent blood clots from reaching the lungs, appear to have evidence of fracturing inside the body, with some fractured fragments traveling to the heart and causing potentially life-threatening complications, according to a report posted online today that will appear in the November 8 print issue of *Archives of Internal Medicine*, one of the JAMA/Archives journals.

Venous thromboembolism, or the formation of blood clots in the veins, occurs in more than 200,000 Americans per year, according to background information in the article. Anti-clotting medications are the standard therapy for patients with this condition. However, some patients cannot take these drugs and others may continue to develop clots despite taking medications. Vena cava filters, devices placed in the vena cava, the large vein returning blood to the heart from the lower body, are designed to trap clots before they travel to the lungs and have been used as an alternate therapy in these patients. Complications associated with these devices include erosion through the wall of the vena cava, along with migration, obstruction and additional clotting of the filter.

One such filter, the Bard Recovery filter, was developed as a device that could either be left in permanently or retrieved as needed and was commercially available from April 2003 through October 2005. The device consisted of two levels of six radially distributed "arms" and "legs" that anchor the filter to the vein and trap any clots, the authors

note. However, these arms and legs reportedly have broken off in some patients. In September 2005, Bard modified the design of the filter to improve its resistance to fracture. The modified Bard G2 cava filter has been implanted in more than 65,000 patients since September 2005, according to information in the article.

Following one initial case of a fractured filter, William Nicholson, M.D., of York Hospital, York, Penn., and colleagues evaluated all 189 patients who received either a Bard Recovery or a Bard G2 vena cava filter at that institution between April 2004 and January 2009. Of these, one patient was pregnant, 35 had died and 10 had already had their filter removed. A total of 80 patients underwent fluoroscopy to assess the integrity of the filter, and those whose filter was fragmented also underwent echocardiography and cardiac computed tomography.

A total of 13 of 80 patients (16 percent) had at least one arm or strut fracture from their filter. This included seven of 28 (25 percent) filters that fractured and embolized (i.e., the fractured piece traveled within the vein) among patients with the first-generation Bard Recovery filter. In five of these seven cases (71 percent), at least one fragment traveled to the heart; three of these patients experienced life-threatening symptoms of rapid heartbeat or fluid buildup around the heart and one experienced sudden death at home.

"While the Bard G2 filter incorporated engineering modifications to reduce these occurrences, 12 percent of the implanted Bard G2 filters also fractured (six of 52)," the authors write. In two of these six cases, the fragment blocked blood flow, one in the vein leading from the liver and one in the lungs. In the other four, the fragments remained close to the filter.

"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 authors write. The average time since filter implantation was about 50 months for patients with the Bard Recovery filter and 24 months for the Bard G2 filter. "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."

"It is essential that patients and their treating physicians be educated about this previously underrecognized and potentially life-threatening complication of these devices," they conclude. "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."

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