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Fracture Rate and Serious Complications of Vena Cava Filters

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ABSTRACT

Purpose: To retrospectively evaluate the prevalence of fracture and fragment embolization of inferior vena cava (IVC) filters. **Methods:** Electronic medical records and imaging studies of all Kaiser Permanente patients who received IVC filters from August 2000 until August 2010 were retrospectively reviewed for filter complications. **Results:** 283 patients received an IVC filter during the study period. 143 patients were deceased, while 140 are living. Among deceased patients, the average age at the time of death was 69.8 ± 15.3 [range: 24.7 - 99.2] years; 55.9% were men; the mean implantation-to-image time was 13.6 ± 20.6 [range: 0 - 92.4] months, and there were no reported major complications attributable to filter migration or fracture at a mean of 16.8 ± 24.8 [range: 0 - 119.6] months following implantation. One of 14 (7.1%) G2 filters perforated the aorta, which already had a stent graft in place. Among those patients still living, the average age was 67.3 ± 15.2 [range: 15.2 - 97.3] years, 47.1% were men, the mean implantation-to-image time was 33.3 ± 36.5 [range: 0.1-141.7] months, and there were no reported major complications at a mean of 35.3 ± 36.5 [range: 0 - 141.7] months following implantation. Three of 60 (5.0%) Trapease filters were found to have at least 1 strut fracture. There were no cases of filter migration or fragment embolization. The overall fracture rate of all filters with an implantation-to-image-time greater than two years (mean implantation-to-image time 4.7 ± 2.7 [range: 2.0 - 11.8] years) was 3 of 67 (4.5%). Bard G2 and G2X filters had a 0% fracture and embolization rate at a mean of 19.0 ± 16.6 [range: 0.07 - 49.5] months after implantation. **Conclusions:** IVC filters, regardless of type, have a low prevalence of fracture and we found no cases of fragment embolization.

Keywords: Venous Thromboembolism; Inferior Vena Cava; IVC Filters; Pulmonary Embolism; Deep Venous Thrombosis; Complications

1. Introduction

Venous thromboembolism is a major U.S. health problem, with an overall age- and sex-adjusted incidence of greater than 1 per 1000 annually [1]. An estimated number of at least 201,000 new cases of venous thromboembolism occur in the U.S. annually, 94,000 of which are pulmonary embolism (PE) [1]. The mortality rate after venous thrombosis is approximately 20% within 1 year and two to four times higher in patients with pulmonary embolism [2-4].

Inferior vena cava (IVC) filters are an alternative therapy for patients who have contraindications to anticoagulation therapy, continued emboli despite anticoagulation therapy, or for those needing PE prophylaxis. Studies have reported fracture prevalence rates that range from 0.05% to 25% [5,6]. Nicholson *et al*., 2010 reported that out of the 80 patients who received Bard (Bard Peripheral Vascular Inc., Tempe AZ) Recovery and G2 filters, 13 (16%) had at least one strut fracture at an average of 37.8 months after implantation. Three patients had life threatening ventricular arrhythmias or tamponade, including one patient who experienced sudden death at home [6].

In 2010, the FDA issued an alert notifying clinicians of adverse events involving IVC filters. Since 2005, the FDA had received 921 device adverse event reports, of which 328 involved device migration, 146 involved embolizations, 70 involved perforation of the IVC, and 56 involved filter fracture. In 2007, almost 167,000 filters were implanted, with an estimated 259,000 IVC filters to be deployed in 2012 [7]. The FDA recommended considering removing filters as soon as protection from PE is no longer needed.

The purpose of this study was to retrospectively evaluate the prevalence of fracture and fragment embolization of IVC filters, and to test the prevailing hypothesis that the fracture rate of Bard Recovery and G2 filters is 16%.

2. Materials and Methods

This study was approved by the Institutional Review Board with a waiver of consent. Electronic medical records and imaging for all patients within an HMO who received IVC filters from August 2000 until August 2010 were retrospectively reviewed, so that every patient would have at least 2 years of clinical follow-up by the time data abstraction was concluded in August 2012. For each patient who received an IVC filter, we recorded the following information: date of filter implantation, date of last clinical assessment, date of first imaging study which documented a filter fracture or migration, date of last imaging study of the abdomen and chest, date of death (if it had occurred by August 2012). We also abstracted clinical information including age at implantation, age at death (if it had occurred), gender, clinical indication for filter placement, the type of filter which was placed, including the model and manufacturer, any mention of filter complication in the EMR or in report of the imaging studies, and cause of death (if it had occurred).

Serious complications from filter placement included fracture of a filter strut and subsequent migration to the heart or lungs. We reviewed all imaging studies of patients from the time of filter placement through August 2012 to determine if a filter fracture, filter migration, or fragment embolization could be identified. This included reviewing all plain films of the chest, abdomen or pelvis, as well as all thoracic and lumber spine films. All CT and MRI studies, which included the chest, abdomen or pelvis, were also reviewed. We recorded the date of the first imaging study in which a filter complication could be demonstrated. This was the implantation-to-complication time. For those patients in whom no filter complication could be demonstrated by an imaging study, we recorded the date of the most recent imaging study documenting an intact filter. This is referred to as the implantation-to-image time (ITIT), which was determined from the patient's most recent abdominal CT or x-ray.

All statistical calculations were performed using SPSS software (IBM Corp, Armonk, NY). Nicholson *et al*. included 80 patients and they reported a 16% fracture rate in Bard IVC filters. If the known percentage is 16.0%, and assuming our fracture rate is 5.0%, a sample size of 65 would give us 90% power to detect a difference in fracture rates.

3. Results

The results are summarized in **Table 1**. 143 patients were deceased, while 140 are living. Among deceased patients, the average age at the time of implantation was 68.5 ± 15.2 [24.6 - 97.5] years. The average age at the time of death was 69.8 ± 15.3 [24.7 - 99.2] years. Among deceased patients, 55.9% were men. Of those who died during the follow-up period up to August 2012, there were 21 patients who had no further imaging of their abdomen or chest prior to their death. For the remaining 122 deceased patients, the mean implantation-to-image time was 13.6 ± 20.6 [0 - 92.4] months, and there were no major complications at a mean of 16.8 ± 24.8 [0 - 119.6] months following implantation. The median follow-up time was 16.6 ± 23.6 [0 - 121.7] months; and 34 (23.8%) of the 143 deceased patients lived for more than 2 years after filter placement. Only one of these patients had their filter removed prior to their death.

Table 1. Patient demographics and IVC filter characteristics.

Variable	All patients receiving IVC filters	
	Deceased (n = 143)	Living (n = 140)
Patient age (at death in the deceased), mean ± SD [Range], y	69.8 ± 15.3 [24.7 - 99.2]	67.3 ± 15.2 [15.2 - 97.3]
Men, No. (%)	80 (55.9)	66 (47.1)
Implantation-to-image time, mean ± SD [Range], mo	13.6 ± 20.6 [0 - 92.4]	33.3 ± 36.5 [0.07 - 141.7]
Duration of no major complications, mean ± SD [Range], mo	16.8 ± 24.8 [0 - 119.6]	35.3 ± 36.5 [0 - 141.7]
Indications for implantation, No. (%)		
DVT/PE	70 (49.0)	63 (45.0)
Cancer	40 (28.0)	9 (6.4)
Other/unknown	14 (9.8)	16 (11.4)
Surgery/trauma	9 (6.3)	31 (22.1)
Coagulopathy	6 (4.2)	15 (10.7)
Prophylaxis	4 (2.8)	6 (4.3)
Cause of Death, No. (%)		
Cancer	78 (54.5)	
Other	26 (18.2)	
Heart disease	18 (12.6)	
Multiple causes	12 (8.4)	
Diabetic complications	5 (3.5)	
Cerebrovascular disease	4 (2.8)	

The primary indication for filter placement in the deceased group included patients with documented DVT/PE with coexisting contraindication for anticoagulation or despite being on anticoagulation in 70 (49.0%) patients; cancer patients at risk for venous thromboembolism in 40 (28.0%); patients with prior surgery or trauma at risk for venous thromboembolism in 9 (6.3%); patients with coagulopathy in 6 (4.2%); patients for prophylaxis against venous thromboembolism in 4 (2.8%); and patients with any other risk factor or no specific indication provided in 14 (9.8%). The cause of death included cancer in 78 (54.5%) patients; other causes such as dementia, cirrhosis, and AIDS in 26 (18.2%) patients; heart disease in 18 (12.6%) patients; multiple causes in 12 (8.4%) patients; diabetic complications in 5 (3.5%) patients; and cerebrovascular disease in 4 (2.8%) patients.

Filter types implanted in the deceased patients are summarized in **Table 2**, and included: 101 (70.6%) Trapease (Cordis Corp., Bridgewater NJ); 14 (9.8%) G2 (Bard Peripheral Vascular Inc., Tempe AZ); 12 (8.4%) Optease (Cordis Corp., Bridgewater NJ); 9 (6.3%) Tulip (Cook Medical Inc., Bloomington IN); 3 (2.1%) Celect (Cook Medical Inc., Bloomington IN); 2 (1.4%) Eclipse (Bard Peripheral Vascular, Inc., Tempe AZ); and 2 (1.4%) Venatech (B. Braun Medical Inc., Bethlehem PA) filters. There were no filter fractures.

One of 14 (7.1%) G2 filters, shown in **Figure 1**, perforated the aorta at 3.1 years after implantation. This patient had an aortic endovascular stent graft in place for an abdominal aortic aneurysm. The filter strut penetrated the aortic wall but did not contact the wall of the stent graft. No clinical complications were associated with this finding.

Among those patients still living, the average age was 67.3 ± 15.2 [15.2 - 97.3] years, 47.1% were men. Ten patients had no further imaging of the abdomen or chest

Table 2. IVC filter types.

IVC Filter Type	Deceased (n = 143)		Living (n = 140)	
	No. (%)	No. of fractured filters	No. (%)	No. of fractured filters
Trapease	101 (70.6)	0	60 (42.9)	3
G2	14 (9.8)	0	40 (28.6)	0
Optease	12 (8.4)	0	15 (10.7)	0
Tulip	9 (6.3)	0	9 (6.4)	0
Celect	3 (2.1)	0	4 (2.9)	0
Eclipse	2 (1.4)	0	3 (2.1)	0
Venatech	2 (1.4)	0	6 (4.3)	0
G2X	0	0	3 (2.1)	0

Figure 1. CT showing G2 filter that perforated the aorta, which had a stent graft in place.

after IVC filter placement. For the remaining 130 patients, the mean implantation-to-image time was 33.3 ± 36.5 [0.07 - 141.7] months, and there were no major complications at a mean of 35.3 ± 36.5 [0 - 141.7] months following implantation (**Table 1**). Twenty-one of these patients had successful removal of their intact filter during the follow-up period.

The primary indication for filter placement in the surviving patients included patients with documented DVT/PE with coexisting contraindication for anticoagulation or despite being on anticoagulation in 63 (45.0%) patients; patients with prior surgery or trauma at risk for venous thromboembolism in 31 (22.1%); patients with coagulopathy in 15 (10.7%); cancer patients at risk for venous thromboembolism in 9 (6.4%); patients for prophylaxis against venous thromboembolism in 6 (4.3%); and patients with any other risk factors or no specific indication provided in 16 (11.4%) (**Table 1**).

Filter types implanted in these patients included: 60 (42.9%) Trapease; 40 (28.6%) G2; 15 (10.7%) Optease; 9 (6.4%) Tulip; 6 (4.3%) Venatech; 4 (2.9%) Celect; 3 (2.1%) Eclipse; and 3 (2.1%) G2X filters (**Table 2**). 3 of 60 (5.0%) Trapease filters were found to have at least 1 strut fracture at 6.7, 9.2, and 9.4 years after implantation (mean 8.47 years from implantation to fracture). One example of a fractured Trapease filter is shown in **Figure 2**. There were no cases of filter migration or fragment embolization.

The overall fracture rate among all filters with an implantation-to-image-time greater than two years (mean ITIT of 4.7 ± 2.7 [2.0 - 11.8] years) was 3 of 67 (4.5%). All 3 of these fractures were Trapease filters. Among all

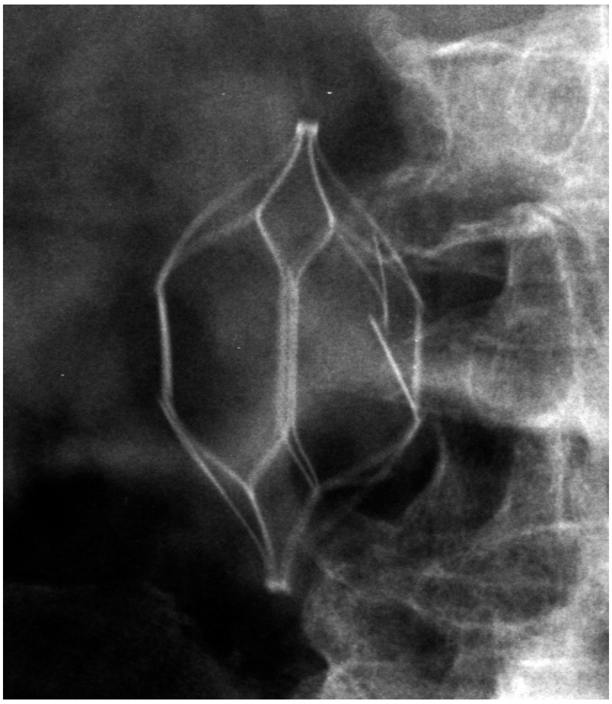

Figure 2. X-ray showing one of three fractured Trapease filters.

Trapease filters, 3 of 80 (3.8%) Trapease filters fractured (mean implantation-to-image time 2.8 ± 3.3 [0 - 11.8] years for all 80 Trapease filters). Bard G2 and G2X filters had a 0% fracture and embolization rate at a mean ITIT of 19.0 ± 16.6 [range: 0.07 - 49.5] months after implantation.

4. Discussion

IVC filter strut fractures, although rarely reported in the literature, could potentially have fatal consequences, including embolization to the heart with subsequent right ventricle perforation or pericardial tamponade [8,9]. Nicholson *et al*. reported a relatively high incidence of fracture with Bard Recovery (25%) and G2 filters (12%) at a mean of 37.8 months after implantation [6]. They predict that G2 filter fractures will rise over time, because of their shorter indwelling time (mean duration of implantation 23.5 months). In our study, the overall fracture rate of all filters with an implantation-to-image-time greater than two years (mean implantation-to-image time 4.7 ± 2.7 [2.0 - 11.8] years) was lower at 3 of 67 (4.5%). All 3 fractures were Trapease filters, which were found to have at least 1 strut fracture at 6.7, 9.2, and 9.4 years after implantation.

Our finding that the fracture rate of Trapease filters was 3 of 80 (3.8%) is consistent with the results of Kalva *et al*., who reported fractures of Trapease device components in 8 (3.0%) of 270 patients over a mean 439 days (range 82 - 845; median 406) [10]. Also consistent with the results of the Kalva *et al* study [10] was that the broken parts of the fractured Trapease filters in our study all remained attached to the main device without migration, perforation of the IVC, or distal embolization. However, in our study, the mean time to strut fracture occurred at a mean 8.4 years after implantation, and none occurred before 6 years. This is considerably longer than that observed by Kalva *et al*., who reported strut fractures in 3 subjects within 1 year of IVC filter placement, and all 8 fractures occurred within 4 years. Since only 30% of their patients had follow-up greater than 1 year, it is not possible to know the long-term fracture rate in their study population [10].

Given that 65,000 G2 filters have already been implanted as of 2010 [6], a fracture rate of 12% implies that 7800 Americans may now already have filter fractures and carry the risk of life-threatening embolization events. However, in our study, the fracture rate for 57 G2 and G2X filters implanted among our patients was 0%, significantly lower than would be expected if the true fracture rate were 12%.

Since the study by Nicholson *et al*. [6], much attention has been brought to the widely used Bard IVC filters. Tam *et al*. retrospectively reviewed Bard Recovery filters and reported 26 short limb filter fractures in 20 of 363 patients (5.5%) at a mean interval from placement to identification of fracture of 33.9 months [11]. Of the 26 limb fractures, 8 fragments migrated into pulmonary arteries, 7 into iliac/femoral veins, 1 into the right ventricle, and 1 into the renal vein. Seven fragments were intracaval near the filter, 1 was extracaval, and 1 could not be located. Of the 20 patients with fractures, 3 died from unrelated causes and 17 were asymptomatic.

Vijay *et al*. reported a total of 63 of 548 fractured Recovery, G2, and G2 Express IVC filters, for an overall fracture rate of 12%, with a distal embolization rate of fractured filter components of 13% at a mean dwell time of 22.7 months [12]. There were no immediate clinically significant complications associated with fracture component embolization or filter removal. A single patient was encountered with symptoms related to his fractured filter.

It is unclear why filter fracture rates would vary from institution to institution. Vijay *et al*. hypothesized that how and where the device was placed could be a major contributing factor, in addition to the various formulations of nitinol, most of which have electropolished surfaces. Potential factors that could accelerate fatigue and predispose filters to fracture include filters placed with elements engaged into renal veins or other vessels, filters that migrate, tilt, or perforate the IVC, and maldeployment [12].

Filter tilt, in addition to adversely affecting clot trapping efficiency, may also alter flow dynamics [13]. M. A.

Singer and S. L. Wang examined the hemodynamic response to thrombus volume and filter tilt of Celect IVC filters inside a model cava [13]. They reported that as filter tilt increased, the cava wall in the direction of filter tilt was subjected to low-velocity flow and gave rise to regions of low wall shear stress, thereby facilitating vascular remodeling. This remodeling may increase the potential for incorporation of the hook of the filter into the cava wall. Zhu *et al*. reported G2 filter limb penetration in 33 of 139 patients, tilt greater than 15˚ in 22 patients, as well as two G2 fractures with a mean indwelling time of 131.8 days [14]. Filter tilt may partially account for the G2 filter in our study found to have perforated the aorta that already had a stent graft in place.

The primary indication for IVC filter placement, as well as patient demographics, may also contribute to fracture rate differences between studies. The patients in our study were older (mean age 69.8 years at death in the deceased; 67.3 in the living) than patients in the study by Nicholson *et al*. (mean age 48.9 years) [6] and Tam *et al*. (mean age 58.9 years) [11]. Additionally, in our study, cancer was the primary indication for IVC filter placement in 28.0% of deceased and 6.4% of living patients. In the study by Nicholson *et al*. [6], malignant neoplasm prophylaxis was the indication for only 4% and 2% of patients receiving Recovery and G2 filters, respectively. In the study by Vijay *et al*. [12], cancer was not listed as one of their indications for filter placement. Given the generally older age and higher incidence of cancer in patients included in this study, many of these patients may not have survived long enough to detect long-term IVC filter complications.

The main limitations of this study were the retrospective study design of reviewing filter implantations and the inconsistent long-term follow-up imaging. This is because there was no formal plan or protocol in place for follow-up in these patients during the study period. To date, there have been no prospective randomized studies comparing all of the various permanent and retrievable filters in regards to their long-term complication rates associated with structural failures. Furthermore, there are no consensus guidelines for the imaging follow-up of IVC filters. In this study, all the patients were members of an HMO for whom all subsequent imaging performed for these patients and their medical records were available for review, as long as the patient remained within the HMO. Therefore, most patients had at least one follow-up imaging study of the abdomen and/or chest which should have detected any major complications, such as fracture of a filter strut with distal embolization. Previous studies did not have as consistent follow-up as described in this study. For example, in the study by Nicholson *et al*. [6], only 80 of the 189 subjects who had a Bard filter were available for the long-term fluoroscopic follow-up. Only 10 of the remaining 109 subjects had their IVC filter removed, and 35 were deceased, but the cause of death was not ascertained. Hence, the integrity of the majority of filters placed by the authors is unknown. Similarly, only 30% of patients in the study by Kalva *et al*. [10] had follow-up for more than 1 year, and according to the authors of the Tam *et al*. study [11], only 50% of their patients had follow-up imaging longer than 4 months. Finally, only those patients presenting back for filter retrieval were included in the study reported by Vijay *et al*. [12]. In contrast, only 21 of the 143 (14.7%) deceased subjects in this study had no follow-up imaging prior to their deaths. Review of their medical records did not describe any complications related to their filter placement and most of these patients died within 6 months of filter placement. Only 10 of the 140 (7.1%) living patients had no subsequent imaging follow-up because they were no longer within the HMO.

5. Conclusion

We report a filter fracture rate of 3 out of 67 (4.5%) in filters with an implantation-to-image time greater than 2 years. All 3 filter fractures were Trapease filters, and no fractures were found in G2 or G2X filters. No life-threatening events occurred in the 3 patients with filter fractures and there were no cases of filter migration or embolization. Further studies or meta-analyses should seek to estimate the fracture and fragment embolization rate of all types of both permanent and retrievable IVC filters, as well as to investigate the mechanical factors that could accelerate filter fatigue and predispose filter fractures. In addition, a systematic screening method should be devised for the large number of patients who currently have IVC filters.

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