Self-reported complication rate for retrievable inferior vena cava filters is significantly higher than for permanent filters

Findings from a review of the United States Food and Drug Administration and Manufacturer and User Facility Device Experience (MAUDE) database reveal that complications occur with significantly higher frequency when retrievable inferior vena cava filters are placed than permanent filters.

Investigators at the Interventional Radiology section at Northwestern University in Chicago, USA, told delegates at the Society of Interventional Radiology’s 39th Annual Scientific Meeting (22–27 March, San Diego, USA) that they aimed to compare the safety of permanent and retrievable inferior vena cava filters by reviewing the self-reported complications with these devices in the MAUDE database from January 2009 – December 2012.

Jessica Andreoli, radiology resident at Northwestern University, Chicago, USA, explained that she recorded the total number of inferior vena cava filter complications self-reported to the MAUDE database during the study period; she specifically categorised the complications by type and rate for all available devices on the market.

The results of the study showed that there were 1,606 reported adverse events involving 1,057 filters. There were 1,394 (86.8%) adverse events involving retrievable inferior vena cava filters and 212 (13.2%) that involved permanent filters (<0.0001).

The number and percentage of each specific adverse event was higher for retrievable inferior vena cava filters when compared to permanent filters. The prevalence of each specific complication varied widely among brands. The most commonly reported adverse events were: fracture (27.1%) for Bard (C R Bard) devices; inferior vena cava penetration (29.9%) for Celect (Cook); and placement difficulties for Optease (Cordis) (30.8%) and Gunther Tulip (Cook, 45%).

“This study suggests that optional filters are inferior to permanent devices in terms of self-reported, device-associated complications,” Andreoli concluded.

Robert J Lewandowski and Robert K Ryu, also from Northwestern University, commented: “Retrievalable inferior vena cava filters were developed to protect patients against fatal pulmonary embolism, yet allow for their removal when no longer indicated. The engineering intent of retrievable filters compared to permanent devices was to be less stable and lower profile so they could be easily removed. The advantage inherent in being retrievalable has rendered these filters to be more prone to device-related complications like migration, fracture, and perforation. Recognising the growing epidemic of device-related complications, the FDA issued a 2010 ‘Initial Communication’ regarding the risk of adverse events associated with long-term use of retrievable filters. ‘Our review of the MAUDE database confirms the differing characteristics of permanent and retrievable inferior vena cava filters. The challenge going forward is to optimise the utilisation of both permanent and retrievable inferior vena cava filters, recognising that there is continued need for both types of devices. Patient care and resource utilisation is optimised when careful prospective decision-making is carried out, as well as meticulous follow-up after filter placement. Further, safe and effective use of ancillary techniques to remove retrievable devices is advocated.’”

Michael Lee, consultant interventional radiologist and professor of Radiology, Beaumont Hospital Radiology Department, Dublin, commented: “Andreoli et al present reported inferior vena cava filter complication rates from the MAUDE database and show a higher reported complication rate for retrievable filters when compared with permanent filters. In total, there were 1,606 reported complications between 2009 and 2012 with 212 complications reported for permanent filters and 1394 reported for retrievable filters. However, we do not know how many permanent and retrievable filters were placed during this time period. Over the last 10 years, many more retrievable filters are placed compared to permanent filters. Therefore, the overall complication rate for retrievable filters placed is unreported in this study. The CIRES Retrievable IVC filter registry reported on 628 retrievable filters placed at CIRES 2013. There were two major complications (<1%) and 14 minor complications (2%). In addition, the significance of the complications reported to the MAUDE database are unknown. For instance, we do know that inferior vena cava penetration (214 events reported for retrievable filters) is usually asymptomatic. It is unclear what the significance of placement issues (reported at 219 events) means. Were these failed placements (unlikely) or technical difficulties related to unfamiliarity with the kit or inexperience on the part of the operator? We also do not know whether these filters were placed by interventional radiologists or other specialties. Similarly, inferior vena cava thrombosis is always going to be reported more frequently with retrievable filters than with permanent because thrombus is going to be imaged at retrieval. Many of these are dealt with at the time of retrieval without the need for prolonged hospitalisation. The most significant events reported were filter embolism and limb embolization were mainly associated with one filter type which has since been withdrawn from the market. Filter tilt (194 events), may or may not be significant depending on whether the degree of tilt hinders retrieval or not. Interestingly, the number of reported venous thromboembolism/ pulmonary embolism events reported (eight for permanent and 22 for retrievable) are low, indicating that filters are fulfilling their primary function.

In summary, this is an interesting study which should be interpreted with caution. A list of reported complications without the denominator of the total number of filters placed is only a snapshot. The significance of the events listed are also unknown making it difficult to draw any meaningful conclusions. The study does however, point out the deficiencies associated with some filter designs and the lack of level one evidence associated with inferior vena cava filter use.”

Survey finds nearly 90% report receiving needlestick injury

Needlestick injury is widespread among interventional radiology staff and trainees and educational training is required, concluded a study presented at the SIR Annual Scientific Meeting.

A nand Prabahkar, Interventional Radiology, Massachusetts General Hospital, Harvard Medical School, Boston, USA, and colleagues, set out to determine the prevalence, types, and causes of needlestick injuries among a group of interventional radiologists.

The investigators also tried to establish how often needlestick injuries are reported and to whom. They further tried to assess the percentage of interventional radiologists who had had training to reduce needlestick injuries.

Prabhahkar told Interventional News: “This study shows the high prevalence of needlestick injuries in interventional radiologists. Since the Centre for Disease Control reports that there are 800,000 needlesticks/year in the USA and 83% of these are preventable, we should focus our efforts on educational programmes to reduce needlesticks. In our study, only 58% of physicians who had a needlestick had received training to reduce needlesticks, demonstrating an area for growth. Following IRB approval, the researchers created a 26-question survey to collect data through the web. They then examined it using statistical software. Twenty eight interventional radiology attendings and fellows were surveyed (20 attendings, 8 fellows) representing a 90% response rate. Eighty six per cent of subjects reported at least one incident of having a needlestick injury, of which 46% were high-risk, involving the needle touching skin or mucosa. The survey further found that 67% of the needlesticks involved a hollow-bore needle and 33% involved a solid needle. Fifty eight per cent of the needlesticks were self-induced and 42% were caused by someone else. The most recent needlestick occurred while passing a needle (42%), loading a needle (25%) or suturing (21%). Subjects reported that the causes of the needlesticks were related to feeling rushed (63%), lack of skill set (38%), lack of assistance (13%), or feeling fatigued (8%). Needlestick injuries were reported to occupational health only 50% of the time.
Transradial access for uterine artery embolization could be “a game changer”

A study, published in the Journal of Vascular and Interventional Radiology, highlights the benefits of the transradial approach to treat uterine fibroids, and investigators find that this technique could be a “game changer”. “Improving patient care and providing advanced treatment options are always on the minds of interventional radiologists. And this could be a game changer for image-guided minimally invasive treatments,” said Aaron M Fischman, an interventional radiologist and assistant professor of Radiology and Surgery, Mount Sinai Medical Center, New York, USA.

Mount Sinai researchers studied the access treatment favoured by some cardiologists for coronary interventions and applied it to uterine artery embolization. By changing the access for treatment from the artery in the groin to the artery in the wrist, the researchers said that the women experienced less pain and trauma than the traditional groin technique—opening the door to potential savings in healthcare costs. Complications related to bleeding at the puncture site are also significantly reduced using this novel approach. Patients are able to walk immediately after treatment, which dramatically improves their experience. “This is just the beginning,” he added, indicating that this technique may also pave the way toward improving other interventional radiology treatments, including those for cancer patients. “Few reports in the literature have explored this application to interventional radiology treatments. This is the first reported use of transradial access for uterine artery embolization,” Fischman added. “Our findings suggest that transradial uterine fibroid embolization offers a safe and effective alternative to transfemoral uterine artery embolization,” he said.

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Continued from page 6

Ryu and Lewandowski responded to Lee’s commentary by saying, “We are grateful for Dr Lee’s erudite and insightful comments. We wholeheartedly agree with him that the total number of inferior vena cava filters placed is unknown, making the context of the abstract difficult to completely understand. However, based on an estimate that 75% of all filters placed are retrievable and that there is a pre-existing “legacy” of permanent filters placed over the past several decades (all of which are currently subject to MAUDE scrutiny), we found that a statistically significant difference in complication rates exist between permanent and retrievable filters. While our conclusion is based on an estimate, it is important to note that this is not a blind estimate but based on an existing market share analysis.

We also agree with Dr Lee that most filter strut perforations seem to be asymptomatic. However, it is unknown what the long term implication, if any, of this finding is.

Other investigators, have reported cases of symptomatic strut perforations and other associated complications. Given these reports, and our own anecdotal experience with symptomatic strut perforations, we are concerned that long-term strut perforations may potentially lead to a higher complication rate, but until we understand this phenomenon more fully, we advocate an aggressive approach to filter retrieval.

Finally, other investigators have reported filter tilt as an important cause of filter retrieval failure (22% according to Dr. Lee’s own publication, and higher in others). We feel strongly that tilt is a critical finding and have reported it accordingly.