Inferior Vena Cava (IVC) Filters: Initial Communication: Risk of Adverse Events with Long Term Use

U.S. Food & Drug Administration

AUDIENCE: Emergency Medicine, Surgery

ISSUE: Since 2005, the FDA has received 921 device adverse event reports involving IVC filters, of which 328 involved device migration, 146 involved embolizations (detachment of device components), 70 involved perforation of the IVC, and 56 involved filter fracture. Some of these events led to adverse clinical outcomes in patients. These types of events may be related to a retrievable filter remaining in the body for long periods of time, beyond the time when the risk of pulmonary embolism (PE) has subsided.

The FDA is concerned that these retrievable IVC filters, intended for short-term placement, are not always removed once a patient’s risk for PE subsides. Known long term risks associated with IVC filters include but are not limited to lower limb deep vein thrombosis (DVT), filter fracture, filter migration, filter embolization and IVC perforation.

BACKGROUND: FDA reviewed the literature and is conducting quantitative decision analysis modeling to evaluate the change in the risk/benefit profile after retrievable IVC filter implantation over time. More information about FDA’s decision analysis model including risk/benefit implantation timeframe suggestions will be made available in an update to this communication as well as in a future publication in a peer-reviewed medical journal.

RECOMMENDATION: FDA recommends that implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from PE is no longer needed.

FDA encourages all physicians involved in the treatment and follow-up of IVC filter recipients to consider the risks and benefits of filter removal for each patient. If a patient has a retrievable IVC filter that should be removed based on his or her individual risk/benefit profile, the primary care physician and/or those providing ongoing patient care should refer the patient for IVC filter removal when feasible and clinically indicated.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[08/09/2010 - Initial Communication [3] - FDA]

SOURCE [4]

Source URL (retrieved on *03/10/2014 - 10:24am*):
http://www.mdtmag.com/news/2010/08/inferior-vena-cava-ivc-filters-initial-communication-risk-adverse-events-long-term-use

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm221676.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm221707.htm