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Look Back Process for Removable Inferior Vena Cava Filter Devices in Response to a Patient Incident

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Abstract

Inferior Vena Cava (IVC) filter is an implanted medical device used in the management of venous thromboembolism when a contraindication to anticoagulation exists, to mitigate embolic complications of proximal deep venous thrombosis or pulmonary emboli.
In January 2017 a caution was released regarding IVC retrievable filters by the Australian Therapeutic Goods Administration (TGA) encouraging the utilization of "formal strategies to address the issue of removal once the risk-benefit profile warrants it" [1].

This paper describes the look-back process undertaken at St. Vincent's Health Network Sydney (SVHN) and the lessons learned through this process. This was undertaken after a complication of a filter occurred at the facility. The individual had suffered no adverse outcomes from the device failure but had raised the question as to the process improvements the facility was undertaking in relation to this internationally reported concern.

The look back process involved one hundred and five (105) patients who had IVCs inserted from June 2009 to April 2018 at SVHNS. Eighty-one patients (77%) who had an IVC filter inserted were identified as requiring appropriate follow-up. In total 69 patients (89%) were contacted by telephone and encouraged to seek follow-up and were also sent letters explaining what was discussed over the telephone. Only12 patients (15%) were unable to be contacted after three attempts.

To date, no patient has raised significant concern from the look back process reported by patients, carers or medical practitioners. This is believed to be the result of a rigorous and thorough process. The process undertaken was based on a Policy Directive from NSW health, as well as the capability, diligence and the compassion of the individual making contact with the patients.

Keywords: Look back process; removable IVC filter device.

Key Questions

1. What is known about the topic?

An Inferior Vena Cava (IVC) filter is commonly inserted endovascularly to prevent lower limb deep vein thromboses propagating proximally to the lungs and is indicated where anticoagulation is contraindicated.

A worldwide issue with device failure required hospitals to assess these patients for consideration for the potential removal of the filter.

Look back processes are not well documented in the literature.

2. What does this paper add?

This paper describes the process undertaken in developing and executing a look back process involving the review of 105 patients and contacting 81 patients, their general practitioner, and referring specialist.

3. What are the implications for practitioners?

Undertaking a successful look back process involves following a rigorous clinical governance framework, guided by an expert advisory panel, strong communications planning and the capabilities of the staff making contact with stakeholders.

Introduction

An Inferior Vena Cava (IVC) filter is a device that is commonly inserted endovascularly into the IVC or infrequently, via the femoral or internal jugular vein. The filter aims to prevent lower limb deep vein thromboses propagating proximally to the lungs and causing a catastrophic pulmonary embolism, and this is indicated where anticoagulation is contraindicated.

This paper describes a look back process initiated by a patient's concerns regarding a fractured filter, at StVincent's Health Network Sydney (SVHN)and the lessons learned through this process.

Background

IVC filters were first developed in the late 1960s and by the early 2000s filters were designed to be more easily retrieved although at around this time complications also began to appear in the literature [2,3,4,5,6,7].

IVC filter devices come in two types: designed for permanent implantation or "optionally removable" filters if this is clinically desirable. For most patient cases the trend has been toward using optionally removable filters for some time now, although the debate continues [8].

In 2010 Nicholson et al investigated the incidence of IVC filter complications with some of the more common filters in use at the time [9]. It was after this paper was published that the FDA (US Food and Drug Administration) issued its advice on 'Inferior Vena Cava (IVC) Filters: Initial Communication: Risk of Adverse Events with Long Term Use' (posted 9 August 2010). The advice was issued following a search of its own adverse events database which showed out of a total of 921 reports involving IVC filters in 2006, '328 involved device migration, 146 involved embolizations (detachment of device components), 70 involved perforations of the IVC, and 56 involved filter fracture'. The recommendation from the FDA was for the 'implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters to consider removing the filter as soon as risk from Pulmonary Embolism aremitigated [10]. The FDA again updated this safety communication in 2014 recommending all patients with an IVC filter are to be considered for removal of the filter once their risk for pulmonary embolism has reduced [11].

In July 2016 Health Canada issued a safety alert encouraging hospitals in Canada to identify patients with a retrievable filter and assess these patients for the potential removal of the filter [12]. This was then followed in January 2017 with the publishing of a bulletin by the Australian Therapeutic Goods Administration (TGA) that contained a safety update on medical devices encouraging 'health workers' and facilities to identify all patients who have a retrievable filter in place and to develop formal plans to remove these once no longer required [13].

The TGA identified 21 adverse incident reports from 2005 to 2016, of these 16 caused severe injury to the patient relating to device limb fracture or migration with no reports of filter related deaths [14]. The following month, February 2017, the TGA listed IVC filters as a high-risk device and published international safety data and minimum reporting standards for manufacturers [15].

To validate the current practices, and the safety and effectiveness of IVC filters, a large multi-center, prospective, open-label, non-randomised investigation of participants (PRESERVE) with IVC filters is underway and expected to be completed in mid-2019. During the study,1,800 participants with an IVC filter inserted between 2005 and 2018 in the United States will be evaluated at regular intervals post-insertion. It is antici-

pated that the findings of this study will assist in determining the future management of IVC filters [16].

In February 2018 a senior interventional radiologist at St Vincent's Hospital Sydney raised a concern with hospital executive regarding a patient incident involving an optionally removable IVC filter device. The incident involved the removal of an older IVC filter device that had fractured from a patient. The patient had suffered no clinically significant complications from the device failure and the metallic fragments were considered to be safely embedded and incorporated into 3 pulmonary artery branches. This was fully disclosed to the patient at the time.

The patient later contacted the hospital concerned that other patients, with older optionally removable filters, could be harmed as a result of possible device failure over the long term.

In response to the incident, an organizational look back process was initiated consistent with guidance in the New South Wales (NSW) Health, Lookback policy directive [17]. The NSW Health Lookback process "is triggered when a notification of a clinical incident or concern from any source leads to the need for the notification, investigation and the management of a group of commonly affected patients. The clinical incident may arise from complications or errors relating to diagnostics, treatment or products that patients have received" [17] .

The SVHN Look back process involved the establishment of an expert advisory group and initial steps included contacting with the Clinical Excellence Commission (CEC) to seek advice and identify whether similar cases had been reported in relation to adverse IVC filter outcomes. The CEC provides leadership in safety and quality in NSW to improve healthcare for patients. No other incidents had been identified at that time but subsequently, the CEC issued a safety bulletin highlighting the risks of long-term use of IVC filters and recommended consideration of the removal of filters once the patient was no longer at riskb [18]. The NSW Chief Health Officer (CHO) was also made aware of the incident and associated look back process and the possibility that the issue had statewide relevance. A statewide look back response was subsequently initiated by the NSW CHO to address the possibility that other patients across NSW might also be at risk.

Method

The SVHN Interventional Radiology Service is provided by the Medical Imaging Department at St Vincent's Hospital, Sydney for public patients and patients from St Vincent's Private Hospital. A list was extracted from the Radiology Information System (RIS) of all patients (public and private) who had an IVC filter inserted and for who had filter removal procedures, which had been inserted from June 2009 to April 2018, to identify as many patients as possible who may require follow-up.

The initial list identified a total of 192 patients, and of these, 127 were public patients, 55 were from the private hospital and 10 were from other referral sources.

A small working group was convened under the leadership of the Director of Medical Services and the Director of Clinical Governance, including the Director of Diagnostics, the Interventional Radiologist, Clinical Governance representatives, and vascular medical and nursing representatives. From this, a recommendation was made to commence a formal Look back Process in line with the NSW Health Look back Policy [19] to identify and manage other potentially affected patients. As a result, an Expert Advisory Group (EAG) was established under the leadership of the Director of Diagnostics.

The EAG, which included clinical experts, senior management and clinical governance support, recommended and coordinated several actions, including, but not limited to

• confirming that IVC filters are only inserted by Interventional Radiologist (IR) and not by any other services including Vascular or Cardiology to ensure all affected patients were captured.

• developing a process for open disclosure for all patients who had had an IVC inserted to ensure appropriate follow-up had or would occur. The Director of Media and Communications was involved in the preparation of media response before patient telephone calls and letters were sent out.

• recommending that the initial contact be made via telephone and then a letter be sent highlighting the need for follow up. At the same time, a letter would be sent to the GP of affected patients and the referring doctors.

• identifying a process for instances where a potentially affected patient was unable to be contacted.

• recommending that follow-up with deceased patient's families was not required as the EAG had been unable to identify in the literature any evidence or known cases of IVC filter failure leading to death in Australia.

• coordinating the revision of the current procedures was undertaken to ensure a rigorous follow-up process post device insertion.

An approved script by the EAG was used by the Clinical Governance Officer (CGO) when calling patients. The script and letters provided to patients were reviewed by the EAG, the Director of Clinical Governance, the Director of Medical Services for approval, and the Diversity Health Coordinator/Health Literacy Officer of SVHNS.

Patient contact commenced on 21st May 2018 and was completed on 18th July, 2018 by the Clinical Governance Officer who is also a senior clinical nurse. Support, such as counseling and psychological support, was made available to all affected patients, their families and/or carers on an individual basis where requested. At the time of writing, no patient, family or carers have requested additional support. Only 4patients contacted the hospital to seek additional clarification regarding the action they needed to take.

Results

An initial review of information systems, booking lists, and medical records resulted in a patient database including192 St Vincent's Sydney campus-wide patients being identified as having had an IVC filter inserted (since 2009). This was further refined (removing duplications and-applicable procedures) resulting in a list of one hundred and five (105) patients who had IVCs inserted from June 2009 to April 2018 at St Vincent's Hospital Sydney and sixty-nine (69) patients from St Vincent's Private Hospital (SVP). SVP followed up its own affected patients.

Of the 105 public patients, twenty-four patients (23%) were either excluded or not required to be contacted due to:

o 9 patients were confirmed to have had their IVC's removed (retrieval rate of 8.5%).

o 11 patients were palliated.

o 4 patients were in nursing homes with complex issues.

In total, 81 public patients (77%) who had an IVC filter inserted were identified as requiring follow-up.

In total 69 patients (89%) were contacted by telephone and encouraged to seek follow-up and were sent letters explaining what was discussed over the telephone. This included several patients from overseas. Patient consent was obtained to send letters on their behalf to their current GP and specialist involved in their care.

Interpreter services were utilized for patients who were from non-English speaking backgrounds and, where indicated in our records, they required an interpreter. Contact details for further clarification and support for patients were made available for the Consumer Feedback Manager and the CGO. Only 4 patients called the Consumer Feedback Manager to clarify what was discussed with them on receipt of the follow-up letter.

General Practitioners (GP) and their specialists were sent a letter explaining the need for patient follow-up. Two GPs contacted the CGO seeking more information.

There were 12 patients (15%) who were still unable to be contacted after three attempts. Several measures were undertaken to try and make contact with these patients. Firstly, they're next of kin and/or carer was contacted to inquire if the patient had more up to date contact details. If this proved unsuccessful the patient's medical records were reviewed to ensure that all possible contact numbers provided by the patient were called. After three failed attempts to contact these 12 patients, a letter was mailed to their last known address.

Discussion

Lookback processes are important to notify patients of health service concerns that may affect their well-being [17]. With IVC filter insertion at SVHNS, a patient raised a concern post removal of their older IVC filter device where failure had occurred. The patient had suffered no clinically significant complications from the device failure but did query whether the health service was responding appropriately to this internationally reported concern.

A clearly articulated policy was invaluable in guiding the practicalities of working through a Look-back process. The input of a diverse stakeholder representative group on the EAG assisted in developing a tight and clinically relevant process. The selection of a senior, compassionate clinician to contact patients was critical in ensuring patients were informed and empowered but not alarmed. Our retrieval rate at 8% was much lower than the retrieval rates reported in the literature of 34% [20].

While the look-back process was in progress a new clinical procedure "IVC Filter Monitoring and Removal Follow-up" was developed, consulted upon and implemented to ensure a more rigorous and systematic process for the timely and appropriate follow up of patients post insertion of IVC filters. The new process includes a:

• clear procedure to be followed by the Interventional Radiologist before, during and after the insertion of an IVC.

• a patient information sheet was developed to be provided to patients before an IVC procedure.

The Look back process also identified a range of other system issues: Inconsistent recording of device type and number on radiological images, information systems, medical records, and device tracking databases which added complexities to the look-back process. The use of inconsistent terminology for the varying IVC filters was also identified as an issue. The EAG, therefore, developed and implemented standardized nomenclature for recording IVC filter type in the local electronic and paper-based information systems to ensure consistency for the recording of these devices.

The EAG also identified that despite the release of cautions and alerts, in this case by the TGA, this information does not always reach other important stakeholders involved in the management of these patients. Examples include non-proceduralists not involved with the initial insertion of the device but are involved in the patient's care, or other referring specialists not directly involved in the insertion of the IVC filter. There was no record at SVHNS that caution had been received.

Conclusion

Following the failure and subsequent removal of an IVC filter in an SVHN patient, a look back process was implemented that involved reviewing 105 patients and contacting 81 patients, including GPs and specialists.

To date, no patient has raised significant concern from the look back process nor any carers or medical practitioners. This is believed to result from the application of a rigorous and thorough look back process, based on an NSW Health, statewide Policy Directive, and the capability, diligence and the compassion of the individual making contact with the patients affected by this issue.

The look back process enabled the facility to review current processes and provided a framework to highlight inefficiencies; identify areas of clinical improvement, and enhance clinical governance of IVC filter utilization at our campus. As a consequence of this process and the development of the "IVC Filter Monitoring and Removal Follow-up" policy, a robust process to track and follow up patients with IVC filters has resulted.

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