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Comparative outcomes of Inferior Vena Cava filters placed at bedside using digital radiography versus conventional fluoroscopy

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ABSTRACT

Purpose: To retrospectively assess the outcomes of Inferior Vena Cava (IVC) filters placed in critically ill patients in the ICU at bedside using digital radiograph (DR) guidance with previous cross-sectional imaging for planning, compared to IVC filters placed by conventional fluoroscopy (CF).
Method and materials: The cohort consisted of 129 IVC filter placements; 48 placed at bedside and 81 placed conventionally from July 2015 to September 2016. Patient demographics, indication, radiation exposures, access site, procedural duration, dwell time, and complications were identified by the EMR. IVC Filter positioning with measurements of tip to renal vein distance and lateral filter tilt were performed when cavograms or post placement CTs were available for review. Statistical analysis was performed using Stata IC 11.2.
Results: Technical success of the procedure was 100% in both groups. Procedural duration was longer at the bedside lasting 14.5 +/- 10.2 versus 6.7 +/- 6.0 min ($p<0.0001$). The bedside DR group had a median radiation exposure of 25 mGy (15–35) and the CF group had mean radiation exposure of 256.94 mGy +/- 158.6. There was no significant difference in distance of IVC tip to renal vein ($p=0.31$), mispositioning ($p=0.59$), degree of filter tilt ($p=0.33$), or rate of complications ($p=0.65$) between the two groups.
Conclusion: IVCF placement at the bedside using DR is comparable to CF with no statistical difference in outcomes based on IVCF positioning, degree of lateral tilt or removal issues. It decreased radiation dose, but with overall increased procedural time.

Introduction

Pulmonary embolism (PE) is associated with high mortality rates, estimated as high as 30%, and is a potentially preventable event.[1,2] Inferior vena cava (IVC) filters provide protection to patients deemed high PE risk who have contraindications or failed anticoagulation.[3–6] IVC filters are conventionally placed in an angiography suite which requires transferring the patient. Transferring critically ill patients carries significant risks in transports. Indeck and colleagues showed 65% of transports result in significant physiological changes to the patient, while Papson and colleagues reported that a median of one unexpected event occurrence per transport.[7,8] Both suggest prioritizing bedside care when possible.

Placement of bedside IVC filters is not new to clinical practice. According to the literature, bedside placement is safe and effective, both by utilizing ultrasound guidance or mobile fluoroscopy. Ultrasound however is operator dependent, with *trans*-abdominal ultrasound having more limitations than intravascular ultrasound.[9,10] Mobile fluoroscopy has limited availability and is not always compatible with bedside configurations. Digital radiographs (DR) are now widely available, portable for bedside use and provide immediate bedside images for review. Use of computed tomography (CT) scans for planning placement of IVC filters has additionally be shown to be safe and effective.[11]

To provide improved services to the critically ill patient, bedside IVC filter placement was prioritized in our practice. The purpose of this study is to retrospectively compare the outcomes of IVC filters placed in critically ill patients in the ICU at the bedside using CT planning with DR guidance to those conventionally placed during the same period.

Methods

Study cohort

This retrospective study was approved by our institutional review

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board, and informed consent waived. A retrospective review of the radiology departments pictorial archiving and communication system (PACS) identified 161 IVC filters placed between July 2015 through September 2016. Exclusion criteria were for placements in which additional procedures simultaneously done and filters not planned for the infra-renal IVC segment. In total, 32 IVC filter placements were excluded due to having multiple procedures performed at the time of placement. Twenty two of the 32 cases with multiple procedures had concurrent angiography to diagnose or treat traumatic injury, 5 had concurrent pulmonary embolism thrombolysis, 4 had concurrent DVT thrombolysis, and 1 had concurrent SVC filter placement. The final cohort consisted of 129 IVC filter placements (48 placed at bedside and 81 placed conventionally). A flow chart of the selection is shown in Fig. 1.

Our institution follows SIR guidelines for IVC filter indications.[4] For critically ill patients deemed high transfer risk (e.g. intubated, pressor support, intra-cranial pressure monitoring), beside placements were performed at the operator's discretion.

Patients identified to the bedside DR group were younger with an average age of 49 +/- 18 years compared to patients in the CF group with an average age of 56 +/- 17 years (p=0.027). Both groups had a slight male predominance with 32 males (66.6%) and 16 females (33.4%) in the bedside DR group and 49 males (60.5%) and 32 females (39.5%) in the CF group. The indications for placement in the bedside DR group consisted of 33 placements (68.8%) for prophylaxis, 10 (10.8%) for DVT, 3 (6.3%) for PE, and 2 (4.2%) for combined DVT with PE. The CF group indications for placement slightly deferred with 18 (22.2%) placed for prophylaxis, 41 (50.6%) for DVT, and 9 (11.1%) for PE and 13 (16.0%) for combined DVT and PE. Patient demographics and indications are summarized in Table 1.

For bedside planning, cross sectional imaging was carefully reviewed. CT was the majority modality comprising 45 of the 48 bedside DR placements. Two had MRI imaging used for planning and one was performed using DR in conjunction with intravascular ultrasound (IVUS). The median time from cross sectional imaging to IVC filter placement was 2 days (range 0 to 259 days) and a majority (13 of 48) being within 1 day. Cross-sectional imaging was used to exclude cavomegaly or anomalous anatomy, and for anatomy deemed appropriate to proceed, define the lowest renal vein confluence and IVC bifurcation as they correspond to the lumbar level on scout images. Finally, the distance from the planned common femoral vein to the lowest dominant renal vein was measured.

Table 1
Patient demographics.

	Bedside IVC Filter	Conventional IVC Filter
Number of patients	48	81
Mean ± SD age, (range)	49 ± 18 (16–82)	56 ± 17 (20–87)
% Male/female	32/16	49/32
Indication		
Prophylaxis	33 (68.8%)	18 (22.2%)
DVT	10 (10.8%)	41 (50.6%)
PE	3 (6.3%)	9 (11.1%)
Combined DVT/PE	2 (4.2%)	13 (16.0%)

At the bedside, a DR plate was positioned behind the patient followed by prepping in the usual sterile fashion. Ultrasound guidance was used to obtain micropuncture access into the common femoral vein. A guidewire was then placed after estimating distance to chest. A DR image was used to confirm IVC placement of the wire by relationship to the right of the lumbar spine and that sufficient wire was placed. The filter sheath was then placed to the pre-measured distance and DR obtained to ascertain lumbar level. Adjustments of the sheath tip were then made based on real time DR measurements until positioned at the desired lumbar spine level. A DR image confirmed filter tip in sheath was at correct lumbar level and subsequently the filter was deployed. A post DR image was obtained to verify correct final position and sheath was removed with pressure used to achieve hemostasis of access site.

Outcome measures

Filter positioning was assessed both in distance to renal veins and for degree of transverse filter tilt. For the bedside placement, filter positioning measurements were performed when retrieval cavograms or post placement CTs were available for review. The distance from the IVC filter tip to the inferior margin of the lowest dominant renal vein was measured

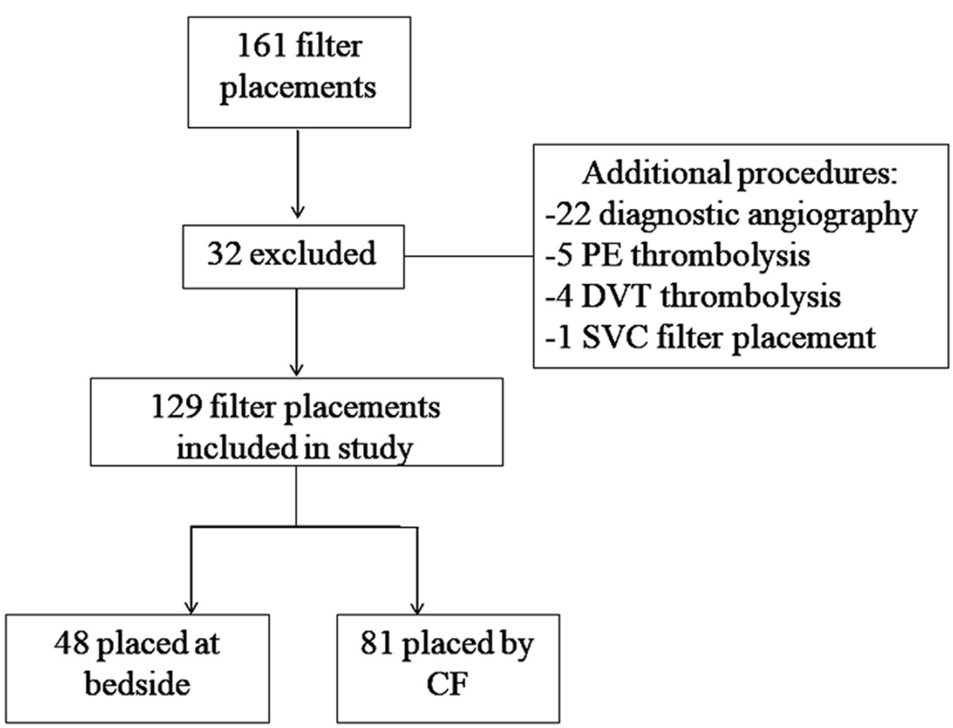

Fig. 1. Flow chart of study selection.

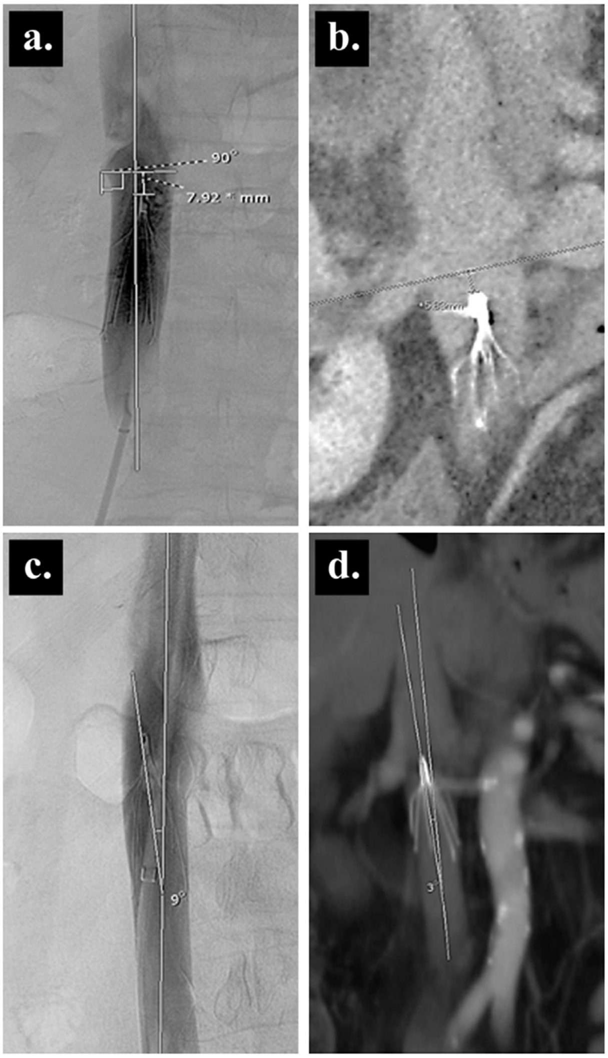

Fig. 2. Distance (upper) and tilt (lower) measurements by cavography (left) and CT (right) imaging.

on AP view for radiography and coronal view for CT imaging. Lateral filter tilt was assessed on AP view for radiography and coronal view for CT imaging, measured as the angle between the long IVC axis to the long filter axis. Representative images depicting measurements can be seen in Fig. 2. Measurements were performed in Synapse PACS (Fuji Medical Systems, Tokyo, Japan).

Given the retrospective nature of the study, procedural times at the bedside could not be consistently identified. Therefore, the time from first to final radiograph was used as a proxy to procedural time. For comparison purposes, the time of initial to final fluoroscopic image was used as a similar proxy for conventionally placed filters. For radiation exposure comparison, the dose at the bedside was calculated by number of radiographs multiplied by 5 mGy, assuming average dose for an abdominal radiograph of 5 mGy.[12,13]

Mispositioning was defined as the IVC filter tip being placed $\geq$ 1 cm superior to the dominant renal vein or within an iliac vein or other aberrant location. Complications included filter failure (PE despite filter protection), IVC thrombosis, filter fracture, filter migration and filter retrieval issues (advanced retrieval techniques or inability to remove).

A fisher's exact test was used to compare rates of filter mispositioning and complications. A student's t-test was used to determine significance for remaining outcomes. Statistical analysis was performed using Stata IC 11.2.

Results

Both groups had 100% technical success rates. Procedural duration was longer at the bedside with a mean procedural duration of 14.5 +/- 10.2 min for the bedside DR group, and 6.7 +/- 6.0 min in the CF group ($p<0.0001$).

The median and mean radiation exposures were 25 mGy (15–35) for the bedside DR group and 256.94 mGy +/- 158.6 for the CF group. Data not amendable to statistical comparison.

For the conventional method the type of filters included the Option (Argon Medical ,Athens, Texas) (n=14), Denali (Bard , Tempe, Arizona) , (n=56) and Celect (Cook Medical , Bloomington, Indiana) (n=11). For the bedside method the filters placed were Option (n=10) ,Denali (n=31) and Celect (n=7) . Filter to renal vein distance and degree of filter tilt did not differ based on placement method. The average distance of the filter tip to the renal vein was 14.5 +/- 16.2 mm in the bedside DR group and 11.5 +/- 11.8 mm in the CF group ($p = 0.25$). No statistical difference in positioning of the IVC filter was found ($p = 0.59$). In the bedside group 0 of 36 with follow up imaging were mispositioned. Ten (27.8%) filters were located at the level of the lowest renal vein and 26 (72.2%) located in the infrarenal segment of the IVC. In the CF group, 4 of 81 (5%) IVC filters placed were considered mispositioned as defined within this study, 26 (32%) were located at the level of the lowest renal vein and 51 (63%) were in the infrarenal segment of the IVC. The bedside DR group had a mean lateral tilt of 5.1 +/- 3.9° and the CF group had a mean lateral tilt of 4.0 +/- 4.4° ($p = 0.33$). The retrieval rates and dwell times were similar between both groups. Thirteen of the 48 filters (27%) placed bedside were retrieved, with a mean dwell time of 170 days (median 136, range 21 to 461 days). Of the 13 filters retrieved, 3 (23%) were noted to have complicated removal. Twenty two of the 81 (27%) conventionally placed IVC filters were retrieved, with a mean dwell time of 206 days (median 195, range 36 to 499 days). Of the 22 filters retrieved, 3 (14%) were noted to have complicated removal. There was no significant difference in rate of complicated removals ($p=0.65$). All complicated removals were contributed to need for additional techniques to capture the filter**.** No complications of IVC thrombosis, filter fracture, or filter migration were identified. See Table 2 for summary of main outcome measures.

Discussion

Bedside IVC filter placement utilizing IVUS is an accepted practice in lieu of traditional fluoroscopically placed IVC filters, though its use seems underutilized secondary to concern for mispositioned filters.[14] This is in spite of several outlined benefits of bedside IVC filter placement among critically ill patients. Hilsop and colleagues reported that pre-procedural computed tomography (CT) planning could reduce the incidence of mispositioned IVC filters during bedside IVUS insertion.[10] Even prior to this, Vesco and colleagues described a method in which CT scans were used to plan fluoroscopic bedside filters without cavography.[11] Here we

Table 2
Main outcome measures.

	Bedside IVC Filter	Conventional IVC Filter	p value
Procedural success	48/48 (100%)	81/81 (100%)	–
Procedural duration (min)	14.5 ± 10.2	6.7 ± 6.0	<0.0001
Distance to renal vein (mm)	14.5 ± 16.2	11.5 ± 11.8	0.25
Filter tilt (degrees)	5.1 ± 3.9	4.0 ± 4.4	0.59
Radiation Exposures (mGy)	25 (15–35)	256.9 ± 158.6	–
Retrieval			
% Removed	13/48 (27%)	22/81 (27%)	–
Retrieval Success	13/13 (100%)	22/22 (100%)	–
Dwell time (days)	170 ± 115	206 ± 123	0.4
Complicated removal	3/13 (23%)	3/22 (14%)	0.65

show bedside placement of IVC filters using DR and cross sectional image planning has similar outcomes to those conventionally placed with comparable safety profile. In this review, both bedside and conventionally placed IVC filters shared 100% technical success rates with no difference both in final positioning within the IVC relative to lowest dominant renal vein and in degree of filter tilt. It is worth noting that by a very stringent definition for mispositioning, defined in this review as the filter tip being 1 cm or more superior to the lowest dominant draining vein margin, that the only 4 meeting this definition were among those conventionally placed, and these were deemed acceptable by the operator at time of placement. Both groups had similar dwell times to retrieval of 170 and 206 days, as well as number retrieved 27% and 23%. The retrieval rates are similar to those reported in the literature during same time periods.[15,16] Both bedside and conventionally placed filters had 3 each IVC filters that were considered complicated removals, noting that these were related to prolonged removal times and use of more advanced techniques. No filter in this study failed retrieval.

This review indicates that IVC filter placement at bedside increases the procedural duration by an average of 7.8 min compared to traditional fluoroscopic placement. However, this is a limited observation based on the time from the first radiograph or fluoroscopic image obtained to the final acquired image. When considering that transfers of the critically ill patients are time consuming, high risk and labor intensive, the 7.8 min lost to procedural time may be accounted for in transfer time and costs. A 1988 study highlights these issues establishing an average transport time of 81 min, with 68% of transfers resulting in increased level of care and the need for 3.3 personnel on average to assist in patient transport.[7] It should be noted that the 81 min reported in the study reflected total round trip time of the transport and the transports were related to diagnostic studies rather than procedures. Unfortunately, the study did not further quantify how those 81 min were utilized making a direct comparison impossible. None the less, transfer of critical patients should be limited where possible and use of DR when CT planning is available is a viable option to place bedside IVC filters.[7,8]

This study found no evidence to suggest an increased patient risk of harm by performing IVC filter placement at bedside over conventional fluoroscopic placement. The bedside placement procedure using DR results in a decreased radiation exposure to the patient and operator. The estimated radiation exposure produced during the bedside placement procedure is 25 mGy based on average number of radiographs needed and the average exposure per radiograph.[12,13] Whereas the average exposure during fluoroscopic placement was shown to be 257 mGy. This indicates that there is a 10 fold increase in radiation exposure in the fluoroscopic placement procedure. Prior commentary related to a study in which bedside placement using a c-arm without venography brings into question concern of misplacing in the aorta.[11] Access was obtained using ultrasound guidance, identifying the common femoral vein in relation to the femoral arteries. Additionally, using micro-puncture access with standard Seldinger technique to exchange for guidewire allowed for clinical assessment of slow versus pulsatile flow as an initial confirmation to venous access. Finally, assessing wire positioning of the wire to the right of spine gave a final confirmation of appropriate IVC selection prior to placement of the filter.

DR for bedside placement allowed for IVC use in patients who otherwise were too unstable for transport. A group of patients worth noting were those with head injuries requiring intra-cranial pressure monitoring with strict pressure requirements and need for elevated head of the bed. The placement of a DR plate is possible in these patients such that the procedural execution was unhindered. While bedside placement facilitates access to the high transfer risk critically ill, not all ICU patients should be considered for bedside placement by DR alone. Patients with no cross-sectional imaging for planning, large clot burden, or patients with variant venous anatomy identified on imaging (cavomegaly, duplicated system, etc.) should not be considered for bedside placement.

This study was limited by its retrospective nature, lack of complete follow up imaging and low retrieval rates. As the placement of bedside filters were not part of a formal research study the data fails to reflect preparation time, as well as total procedure time from needle access to completion of bandage application, and similarly does not look at local transfer times of the critically ill patients to and from the fluoroscopy suite. Just over half those placed at the bedside had either CT imaging and / or were retrieved to provide a more comprehensive assessment of post placement outcomes. Similarly, the overall low retrieval rates in both groups limits full assessment of retrievability. Low retrieval rates are partly attributed to a 21% and 22% associated mortality rate, as well as 33% and 35% of patients being lost to follow up in the bedside DR and conventional groups, respectively.

Conclusion

IVC filter placement at the bedside using digital radiography is comparable to IVC filter placement using conventional fluoroscopy with no appreciated outcome differences based on IVC positioning, degree of lateral tilt or removal issues. IVC filter placement at bedside comes with a tradeoff of decreased radiation dose to both the operator and patient, however, with overall increased procedural time. Lastly, providing bedside placement of IVC filters provides a means to protect the critically ill patient from undergoing labor-intensive high risks transports.

Declaration of competing interest

None of the authors has a conflict of interest related to this research .

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