Comparative analysis of technical success rates and procedural complication rates of bedside inferior vena cava filter placement by intraprocedural imaging modality

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ABSTRACT

Objective: Transabdominal duplex ultrasound, intravascular ultrasound (IVUS), and fluoroscopy have been used to assist with inferior vena cava filter (IVCF) placement since the late 1990s. We sought to compare the technical success and procedural complications of bedside placement of IVCF by the three commonly used modalities, namely, duplex ultrasound, IVUS, and combined IVUS and fluoroscopy.

Methods: All published reports including prospective and retrospective cohort studies and case series with a minimum of 10 patients from inception to August 2017 were identified by an electronic search of PubMed and Embase. The studies were then pooled to create a sample of patient data for statistical analysis. Bonferroni correction was used for comparison of the three groups. Values of $P < .017$ (two tailed) were considered statistically significant for the pairwise comparisons.

Results: A total of 21 studies comprising 2166 patients were identified. No significant differences were found in technical success and complication rates between the duplex ultrasound and IVUS arm, the combined IVUS and IVUS with fluoroscopy arm, or the duplex ultrasound and the combined IVUS with fluoroscopy arm. However, there was a trend toward decreased complication rates in the duplex ultrasound arm compared with the other two arms. A trend toward increased technical success was also observed in the combined IVUS and fluoroscopy arm compared with the other two arms.

Conclusions: There are no significant differences in the technical success and complication rates between the three commonly used modalities of bedside IVCF placement. (J Vasc Surg: Venous and Lym Dis 2019;7:601-9.)

Keywords: Inferior vena cava bedside placement; Conventional fluoroscopy; Complications; Technical success

Pulmonary embolism (PE) and deep venous thrombosis (DVT), collectively known as venous thromboembolism (VTE), are important causes of disability and death.[1,2] The highest risk of VTE exists in critically ill patients who have contraindications to anticoagulation; PE is diagnosed in approximately 4% to 6% of these patients.[3-5] Studies have also shown that PE in critically ill patients tends to occur during the first week after hospital admission.[3,6] Guideline-supported indications for inferior vena cava filter (IVCF) placement include acute VTE and an absolute contraindication to anticoagulation or documented failure of anticoagulation.[7] Nonetheless, many IVCFs are also being implanted for other indications, such as prophylaxis in patients deemed to be at high risk for development of VTE.[8] Unfortunately, in daily clinical practice, anticoagulation of the critically ill patient is a challenge because of elevated bleeding risk and the need for interventions necessitating interruption of anticoagulation. Patients who are critically ill, morbidly obese patients, and polytrauma patients might not be ideal candidates for transport to the fluoroscopy suite. In such patients, bedside IVCF placement can be considered a safe and alternative approach. It is unclear whether one modality is superior to another in terms of IVCF placement at the bedside, so we aimed to compare the technical success and complication rates of the common modalities.

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METHODS

Literature search strategy

A systematic review of published literature was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.[9] MEDLINE and Embase (through Ovid) and Cochrane Central databases were searched until August 2017. Relevant MeSH headings and variations of the words "inferior vena cava filter bedside," "inferior vena cava intensive care unit," "IVC filter bedside," and "IVC filter intensive care unit" were used.

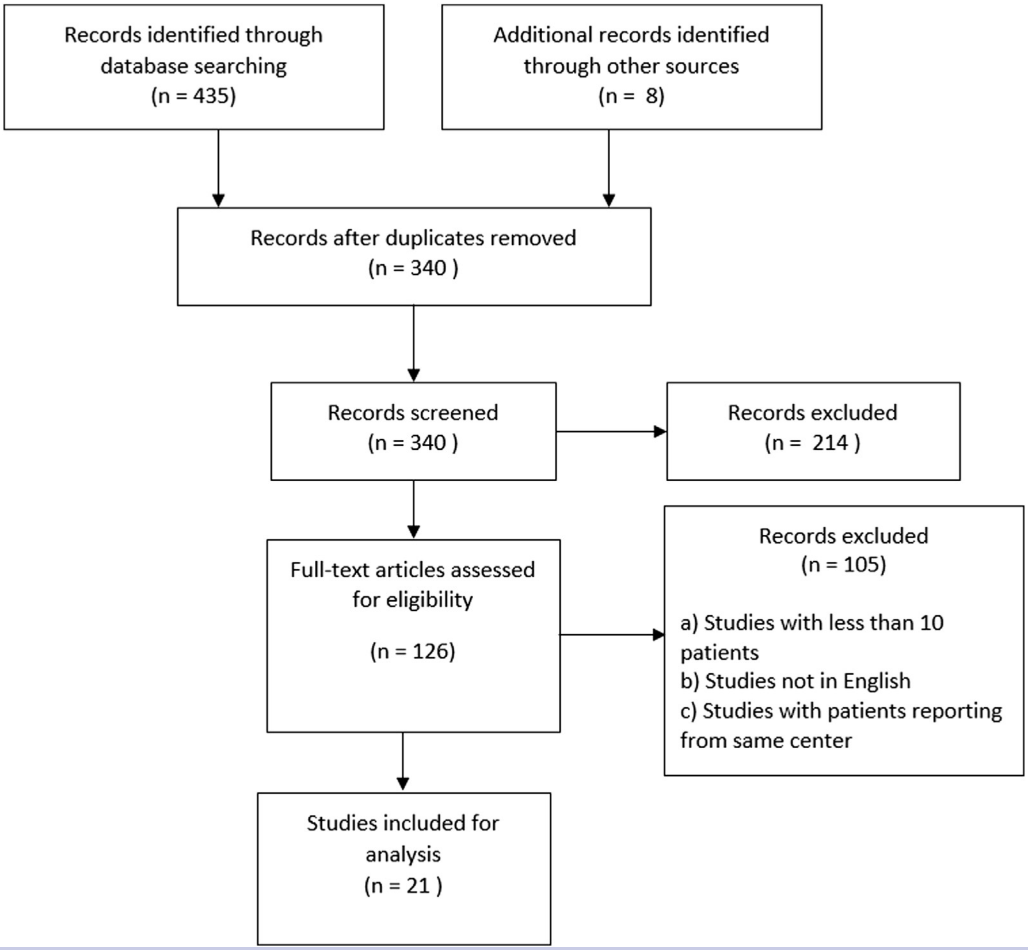

Fig 1. Flow diagram of study selection process.

Citations were screened at the title and abstract level, limited to English and human subjects. Two authors (P.S. and K.S.) performed the search independently, and any discrepancies were resolved by discussion. The reference lists of all retrieved articles were reviewed for further identification of potentially relevant studies and assessed using the inclusion and exclusion criteria. Protocol and informed consent review needing approval by the Institutional Review Board was not required, and no human subjects were involved. The technical success and complication rates are being compared between the three modalities of IVCF placement.

Selection criteria

We deemed studies eligible if they fulfilled the following prespecified criteria.

Inclusion criteria. The inclusion criteria were studies reporting data on the placement of an IVCF at the bedside using bedside ultrasound or intravascular ultrasound (IVUS), studies reporting data for at least 10 patients, and studies written in English.

Exclusion criteria. The exclusion criteria were duplicate publication or overlap of patients and individual case reports or case series with a sample size of <10.

Data extraction

Data were gathered through a predefined extraction sheet including first author, year and journal of publication, and number of patients included and the setting in which IVCF placement was performed (bedside placement and fluoroscopy guided). The following items were extracted from the studies wherever available: patients' characteristics (age, sex, and comorbidities), procedural details, safety, and efficacy outcomes (technical success and complications). Accuracy and validity were assessed by the two reviewers (P.S. and S.S.), and any disagreements in judgment were resolved through consensus. Fig 1 shows the flow diagram of the study selection process.

Study end points

In our systematic review and pooled analysis, we evaluated the following end points: technical success and complication rate.

Statistical analysis

The study variables were described using sample mean with standard deviation or proportion as appropriate. The numbers of complications and technical success

Table I. Baseline characteristics of included studies

Study	Country	Design	Duration of enrollment	Female, %	No.	Age, years	Follow-up, months	Technical success, No. (%)	Complications, No. (%)
Duplex ultrasound									
Benjamin et al[10]	United States	Prospective	NA	14.3	23	46	0.4	23 (100)	1 (4.35)
Corriere et al[11]	United States	Retrospective	1995-2002	NA	382	40.6	63	372 (97.38)	7 (1.83)
Taccone et al[12]	Belgium	Registry based	2013-2014	35	60	44 (28-58)	0.56	53 (88.33)	NA
Cosgrove[13]	United States	Retrospective	2009-2014	NA	83	NA	In-hospital	75 (90.36)	NA
Liu et al[14]	China	Retrospective	2011-2013	56.5	46	60.77 ± 13.8	6	43 (93.48)	2 (4.35)
Cadavid et al[15]	Multinational	Prospective	2011-2012	13.5	8	35.4 ± 16.2	In-hospital	8 (100)	1 (12.5)
Sato et al[16]	United States	Prospective	1996-1997	39.13	46	46 ± 19	In-hospital	45 (97.83)	1 (2.17)
IVUS									
Aidinian et al[17]	United States	Retrospective	2003-2007	7.2	14	26 ± 5.1	1	13 (92.86)	1 (7.14)
Ebaugh et al[18]	United States	Retrospective	1998-2000	42.3	26	55	1.5	24 (92.31)	2 (7.69)
Hodgkiss et al[19]	United States	Retrospective	2006-2009	30.92	97	51	In-hospital	97 (100)	16 (16.49)
Killingsworth et al[20]	United States	Prospective	2008-2008	24	109	45 ± 18.4	12	107 (98.17)	6 (5.50)
Ganguli et al[21]	United States	Retrospective	2009-2011	35	117	50.8 ± 18.2	15.4	112 (95.73)	28 (23.93)
Hislop et al[22]	United States	Retrospective	2010-2011	19	46	47	In-hospital	46 (100)	0
Gamblin et al[23]	United States	Prospective	1999-2000	NA	36	NA	In-hospital	34 (94.44)	0
Gunn et al[24]	United States	Retrospective	2005-2011	39.4	99	58.8	In-hospital	93 (93.94)	8 (8.08)
Bonn et al[25]	United States	Retrospective	NA	50	30	56	In-hospital	30 (100)	0
Glocker et al[26]	United States	Retrospective	2008-2012	30	398	76.5 ± 19.4	1	393 (98.74)	12 (3.02)
Ferraro et al[27]	Italy	Retrospective	1999-2013	45.16	62	47.84	1	60 (96.77)	7 (11.29)
Fluoroscopy and IVUS									
Tola et al[28]	United States	Prospective	1997-1998	24	25	52.6	0.5	25 (100)	0
Paton et al[29]	United States	Prospective	1996-2005	38.5	403	42.9±17.4	In-hospital	400 (99.26)	57 (14.14)
Gonzalez et al[30]	United States	Retrospective	1999-2003	NA	56	38.6	In-hospital	54 (96.43)	2 (3.57)

IVUS, Intravascular ultrasound; *NA*, not applicable.

Table II. Estimated rates ratio for technical success of three modalities

Differences of group least squares means					
Group	Group	Estimate	Standard error	z value	Pr > |z|
Duplex ultrasound	IVUS	−0.01933	0.05108	−0.38	.7052
Duplex ultrasound	IVUS and fluoroscopy	−0.03540	0.06086	−0.58	.5608
IVUS	IVUS and fluoroscopy	−0.01607	0.05551	−0.29	.7721

IVUS, Intravascular ultrasound.
Bonferroni correction was used for comparisons of the three arms. Values of $P < .017$ (two tailed) were considered statistically significant for the pairwise comparisons.

Table III. Estimated rates ratio for complications of three modalities

Differences of group least squares means					
Group	Group	Estimate	Standard error	*z* value	Pr > |z|
Duplex ultrasound	IVUS	−0.8656	0.6064	−1.43	.1535
Duplex ultrasound	IVUS and fluoroscopy	−0.7740	0.7336	−1.05	.2914
IVUS	IVUS and fluoroscopy	0.09165	0.5482	0.17	.8672

IVUS, Intravascular ultrasound.
Bonferroni correction was used for comparisons of the three arms. Values of $P < .017$ (two tailed) were considered statistically significant for the pairwise comparisons.

are the count variables of those events during a certain period. A negative binomial regression was performed to compare the rates of complications and technical success between the three arms (duplex ultrasound, IVUS, IVUS and fluoroscopy). Pairwise comparisons were conducted between those three arms. Values of $P < .05$ (two tailed) were considered statistically significant. SAS 9.4 software (SAS Institute, Cary, NC) was used for all analyses.

RESULTS

A total of 21 studies comprising 2166 patients were identified. A total of 648 patients were included in the duplex ultrasound only arm, 1034 patients in the IVUS only arm, and 484 patients in the combined IVUS and fluoroscopy arm. Baseline characteristics including demographics and duration of follow-up of the involved studies are described in Table I. The estimated technical success rate of the IVUS arm is about 1.02 ($P = .7052$) times as much as the rate of the duplex ultrasound arm. The estimated technical success rate is about 1.04 ($P = .5608$) times higher in the combined IVUS and fluoroscopy arm than in the duplex ultrasound arm. The estimated technical success rate of combined IVUS and fluoroscopy is about 1.02 ($P = .7721$) times as much as the rate of the IVUS arm. Estimated rates ratio for technical success and complication rates of the three modalities are shown in Tables II and III.

Table IV. Complications in the duplex ultrasound arm

Study	Year	Type of filter	Technical difficulties or complications
Benjamin et al[10]	1999	Titanium Greenfield	Suprarenal placement—1
			Could not be adequately imaged because of bowel gas pattern—2
Corriere et al[11]	2005	NA	Inadequate IVC imaging—57
			Inadequate placement
			Iliac vein deployment—6
			Filter angulation >15 degrees—2
			Inadvertent suprarenal deployment—1
			Incomplete filter opening—1
Taccone et al[12]	2015	Angel catheter (self-expanding nitinol filter)	Device not visualized after placement, so immediately retrieved—1
			Kinked guidewire—1
			Filter migration—2
			Inadvertent removal of the Angel catheter—4
Cosgrove[13]	NA	Permanent stainless steel or titanium Greenfield filter kit	Inability to pass the wire through the iliac system—5
			Inability to adequately visualize the carrier system—3
			More than one vertebral body outside the L2-3 landmark—5
Liu et al[14]	2015	Aegisy filter	Filter replacement due to poor device location—1
			Filter tilt—2
Cadavid et al[15]	2013	Angel catheter	Accidental removal—1
Sato et al[16]	1999	VenaTech LGM filters	Inadequate ultrasound visualization—7
			Suprarenal IVC placement—1

IVC, Inferior vena cava; *NA,* not applicable.

Table V. Complications in the intravascular ultrasound (IVUS) arm

Study	Year	Type of filter	Technical difficulties or complications
Aidinian et al[17]	2009	Günther Tulip	Common iliac vein deployment—1
		OptEase	
Ebaugh et al[18]	2001	Over-the-wire Greenfield	Femoral vein insertion site thrombosis at 30 days—1
			Symptomatic caval thrombosis 55 days after placement—1
			Left common iliac vein placement—1
			Filter tilt—1
Hodgkiss et al[19]	2012		Filter malposition—6
			Filter tilt—10
Killingsworth et al[20]	2010	Günther Tulip	Inadequate visualization—2
		Greenfield	Filter malposition—3
			Common femoral AV fistula—1
			Minor axial tilt—2
Ganguli et al[21]	2017	Option	Malposition—4
		Celect	Severe tilt—1
		Bard G2/G2X	IVC thrombosis—4
		Eclipse	DVT—16
		Günther Tulip	PE—6
		OptEase	IVC stenosis—1
Hislop et al[22]	2014	Cook Celect	None
Gamblin et al[23]	2003	Stainless steel Greenfield	Inadequate imaging—2
			Inadequate positioning—3
Gunn et al[24]	2013	Celect	Malpositioned filters—6 (4 in the iliac veins and 2 in the suprarenal IVC)
		TrapEase	Groin hematoma—4
		Günther Tulip	Venous access site DVT—2
		OptEase	Filter tilt >15 degrees—2
		Option	
		Simon nitinol	
Bonn et al[25]	1999	Titanium Greenfield	None
		Bird's Nest	
		VenaTech LGM	
Glocker et al[26]	2014	Stainless steel Greenfield	Malpositioned filter—3
		Celect	Filter tilt—4
		Günther Tulip	AV fistula—2
			Insertion site thrombosis—2
			Hematoma—1
Ferraro et al[27]	2014	Angiocor ADI	Cranial migration—3
		Cordis KEEPER	Caudal migration—1
		Antheor DC	Caval thrombosis—1
		Braun VenaTech LGM	Residual clot—3
		Braun LPI	Endothelial adhesion—11
		Cordis temporary vena cava filter Prolyser	Microbial colonization of the filter in absence of clinical signs of infection—2
		Braun LGT	DVT—5
		Braun Tempofilter II	Pneumothorax—1
		Antheor TC	
		ALN	

AV, Arteriovenous; *DVT,* deep venous thrombosis; *IVC,* inferior vena cava; *PE,* pulmonary embolism.

Table VI. Complications in the combined fluoroscopy and intravascular ultrasound (IVUS) arm

Study	Year	Type of filter	Technical difficulties or complications
Tola et al[28]	1999	Greenfield	None
		B. Braun VenaTech	
Paton et al[29]	2006	Titanium Greenfield	Misplacement of the filter—2
		Stainless steel Greenfield	Groin hematoma—1
		VenaTech LGM	Right ventricular perforation—1
		Bird's Nest	Post-VCF DVT—38 (insertion site—14)
		Simon nitinol	Post-VCF PE—2
		TrapEase	Caval occlusion—4
		Recovery	Caval thrombosis—7
		OptEase	
		Günther Tulip	
		G2	
Gonzalez et al[30]	2006	Stainless steel Kimray-Greenfield	Filter migration—1
			Incorrect filter deployment—1

DVT, Deep venous thrombosis; *PE,* pulmonary embolism; *VCF,* vena cava filter.

With regard to complications, the estimated complication rate for the IVUS arm is about 2.4 (P = .1535) times as much as the rate for the duplex ultrasound arm. The estimated complication rate is about 2.2 (P = .2914) times higher in the combined IVUS and fluoroscopy arm than in the duplex ultrasound arm. The estimated complication rate for IVUS is 1.1 (P = .8672) times that of the combined IVUS and fluoroscopy arm. The individual complications in each study are described in Tables IV to VI. Table VII shows different variables summarized using the median with upper and lower quartiles. Figs 2 and 3 show the plots of means with standard error bars for the complications as well as technical success. Vascular surgeons placed 37.6% of the filters, whereas trauma surgeons were the operators in 20.8% of the population, followed by general surgeons and interventional radiologists in 4.1%. In 33.4% of the studies, it is unclear as to who the operators were.

DISCUSSION

IVCFs are currently being used in a wide variety of patients. The three most common routes of implantation of the IVCF are conventional fluoroscopy and contrast venography, transabdominal ultrasound guidance, and IVUS guidance. Bedside placement of the IVCF has been in practice since the late 1990s as reported by Rose et al[31] in 1997 with a series of five patients. It is unclear as to what approach is better in placing an IVCF at the bedside to achieve high rates of technical success with minimal short-term complications. A subset of the population, including critically ill patients who are morbidly obese and taking multiple vasopressor medications and polytrauma patients, cannot always be safely transported back and forth to the fluoroscopy suite because of the risk of ventilator complications and hemodynamic instability. In polytrauma patients, multiple risk factors have been identified that place them at high risk for development of VTE.

Table VII. Summary statistics

	Overall (N = 21)		Duplex ultrasound (n = 7)		IVUS (n = 11)		IVUS and fluoroscopy (n=3)	
Factor	No.	Statistics	No.	Statistics	No.	Statistics	No.	Statistics
No.	21	56.0 (30.0-99.0)	7	46.0 (23.0-83.0)	11	62.0 (30.0-109.0)	3	56.0 (25.0-403.0)
Minor complications	19	2.0 (1.00-8.0)	5	1.00 (1.00-2.0)	11	6.0 (0.00-12.0)	3	2.0 (0.00-57.0)
Minor complication rate	19	0.04 (0.02-0.11)	5	0.04 (0.02-0.04)	11	0.07 (0.00-0.11)	3	0.04 (0.00,0.14)
Technical success	21	53.0 (30.0-97.0)	7	45.0 (23.0-75.0)	11	60.0 (30.0-107.0)	3	54.0 (25.0-400.0)
Technical success rate	21	0.97 (0.94-1.00)	7	0.97 (0.90-1.00)	11	0.97 (0.94-1.00)	3	0.99 (0.96-1.00)

IVUS, Intravascular ultrasound.
Statistics presented as median (P25-P75).

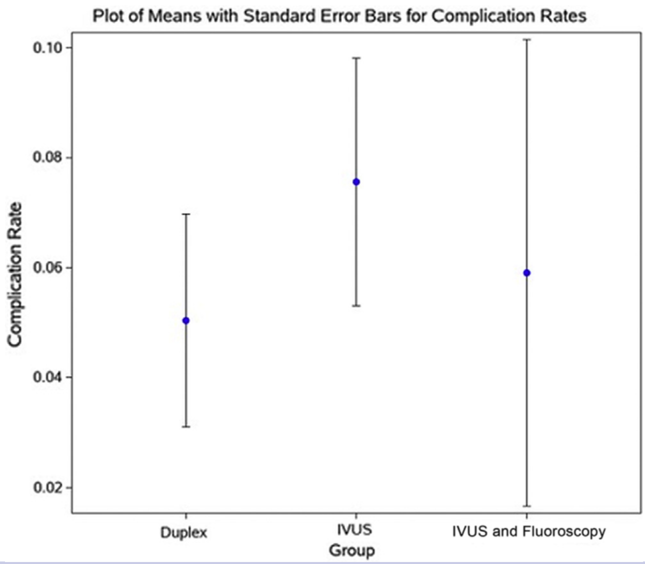

Fig 2. Plots of means with standard error bars for complications. *IVUS*, Intravascular ultrasound.

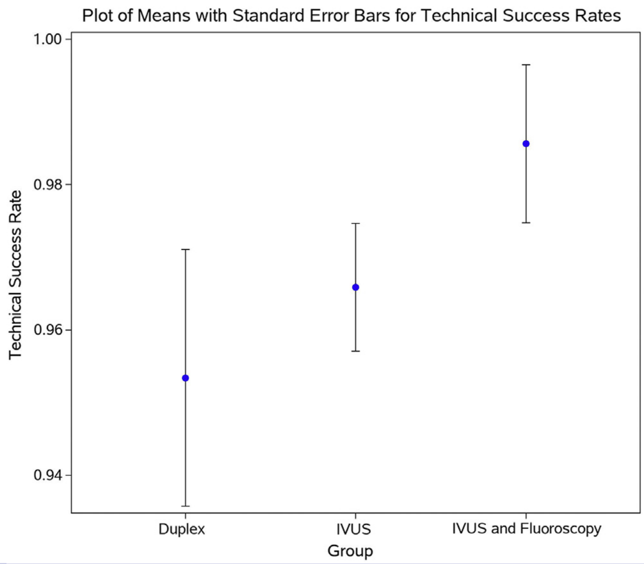

Fig 3. Plots of means with standard error bars for technical success. *IVUS*, Intravascular ultrasound.

Bedside placement of IVCFs has many drawbacks, including but not limited to improper positioning or partial deployment of the filter, femoral arteriovenous fistula, penetration of the inferior vena cava wall by hooks or struts of filters, and migration to heart or lungs, and the chances of infection are higher. However, most of these complications hold good for conventional placement of the IVCF too, but one would assume a lower overall incidence of short-term or periprocedural complications because it is placed under fluoroscopy. Besides, bedside IVCF placement has advantages over conventional methods in that radiation exposure, although minimal, can be avoided. Similarly, the need for intravenous administration of contrast material is also eliminated, and this is crucial in critically ill patients who are taking vasopressors and have a risk for development of renal failure.

One of the major limiting factors of using duplex ultrasound for filter placement is the ability to adequately visualize the IVCF with surface ultrasound imaging. Friedland et al[32] reported a series of cases that involved ultrasound imaging of the vena cava before interruption with an adequate visualization rate of 98.5%. However, in trauma patients, transabdominal ultrasound scanning might be challenging, which can be attributed to the aggressive resuscitation in critically ill patients that leads to soft tissue edema. However, Sato et al[16] showed that IVCF placement can be successfully completed in <15 minutes once it is satisfactorily visualized.

IVCFs were associated with a significant decrease in the early incidence of PE compared with anticoagulation alone at short-term follow-up; however, the difference was not statistically significant after 2 years.[33] It has also been shown that in spite of a reduction in the incidence of PE in the short term with IVCFs, an increase in recurrent DVT occurred in patients who had IVCFs placed compared with the population who did not have IVCFs.[34]

Liu et al[14] recommended that patients should be fasting and should receive an enema before the bedside IVCF placement, and visualization of the renal vein-inferior vena cava junction and marking of the outer body surface may help guide accurate positioning of the filter. The major disadvantage of the use of IVUS guidance for the placement of IVCFs is the relatively high incidence of filter malposition early in the practitioner's experience. This has been found to be as high as 8%.[17,20] This was largely due to misinterpretation of venous anatomy seen in cross-sectional detail using IVUS. This could be one of the reasons for the high incidence of complications for the IVUS and fluoroscopy combined arm. However, the high incidence of postinsertion DVT raises the question of whether the DVT was due to the placement of the IVCF. Velmahos et al[35] performed a meta-analysis of 73 articles relevant to DVT prophylaxis and found that high-risk patients have an 11.8% incidence of DVT and 1.5% incidence of PE. Therefore, one could argue that postinsertion DVT is likely not to be from the filter, and it is not surprising to see such high rates as they have a higher thrombosis risk overall. Filter tilt reporting is not uniform, and some studies have reported it close to 13%.[19]

Technical success and procedural complications. The technical success of bedside IVCF placement and fluoroscopy placement has been comparable. A retrospective study by Ganguli et al[21] showed that bedside placement of the IVUS-guided IVCF is a safe procedure, and our study results concur with that. The usefulness of bedside placement of the IVCF is thus known; however, the best imaging technique for this procedure has not yet been well studied. Ashley et al[36] showed IVUS to be superior to contrast venography in accuracy of imaging used during vena cava filter placement. In employing the IVUS technique, Jacobs et al[37] recommended that fluoroscopic imaging be combined with IVUS in the operator's early experience as this will allow the operator to correlate the accuracy of IVUS imaging of the inferior vena cava and localization of the renal veins with contrast venography as well as demonstrate the stability and accuracy of filter deployment after delivery sheath positioning as it occurs using the IVUS-guided technique alone. Another advantage besides the acceptable technical success and complication rates is that bedside IVCF placement is cost-effective compared with conventional fluoroscopy.[10,18] We report a comprehensive systematic review of bedside IVCF placement by the three commonly used modalities, the first of its kind in the literature. The individual complications in each study are outlined in Tables IV to VI.

Limitations. One of the major limitations of our study is that it was not feasible to define technical success and the complications as data reporting was not uniform and studies were conducted during a wide period, starting from 1997 to 2017. The techniques have also undergone considerable advances during this period. Although this is the largest pooled analysis of patients looking at the outcomes based on the bedside placement of IVCFs by the common imaging modalities, the study population is still small. Data have been largely derived from case series and retrospective studies, so heterogeneity or publication bias assessment among the studies could not be performed.

CONCLUSIONS

Larger registries and studies are needed to establish the safety and efficacy of bedside IVCF placement by the various imaging modalities.

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AUTHOR CONTRIBUTIONS

Conception and design: PS, ML, NA
Analysis and interpretation: PS, KS, XW
Data collection: PS, KS, XW, SS
Writing the article: PS, KS, ML
Critical revision of the article: PS, KS, XW, SS, NA
Final approval of the article: PS, KS, ML, XW, SS, NA
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