

The Effectiveness of Prophylactic Inferior Vena Cava Filter Insertion in Trauma Patients

This article was published in the following Scient Open Access Journal:

Integrative Trauma and Emergency Medicine

Received May 17, 2018; Accepted June 06, 2018; Published June 15, 2018

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Abstract

Background/objective: Patients with trauma are at risk for venous thromboembolism, such as deep venous thrombosis and pulmonary embolisms (PEs), and using inferior vena cava (IVC) filters or anticoagulants may decrease the risks. This study aims to compare the effectiveness of the prophylactic insertion of IVC filters in patients with femur or pelvic fractures and to determine if the IVC filter insertion, combined with prophylactic anticoagulation, is superior to prophylactic anticoagulation use in preventing thromboembolic events in trauma patients.

Methods: This is an observational comparative study. The enrolled patients were observed for the development of PEs, and those who had an IVC filter inserted and those who didn't have IVC filter inserted were compared; in relation to the development of PE and death. The study was conducted between April 2015 and October 2016 among 36 trauma patients at Care National Hospital in Riyadh, Saudi Arabia. Thirty six patients were admitted to the intensive care unit (ICU) with pelvic or femur fractures. The patients were selected using the convenience sampling technique. Data were analysed using SPSS version 22; as a descriptive analysis and chi-square test for comparison.

Results: A total of 36 patients were admitted to the ICU during the study period. The mean patients' age was 34 ± 10 years, and all ICU admissions were males. The mode of trauma was attributed to; road traffic accidents (RTA) 83.3%, falls from a varying heights 13.9%, and gunshots 2.8%. The patients with trauma were classified into three types according to the area of the fractures: pelvic fractures in 19 (52.8%), femur fractures in 15 (41.7%), and long bone fractures in 15 (41.7%), where 10 (27.8%) had two fractures in and 1 (2.8%) had three. Thirty patients had IVC filters (83.3%), and none of them were positive for a PE ($p = 0.02$). Among 24 patients who used anticoagulants, PE was only reported in 1 (4.2%; $p = 0.6$); 3 patients died during the study but only one died of major PE, and this patient had started anticoagulation but had no IVC filters inserted; the second died due to septic shock and severe acute respiratory distress syndrome (ARDS); and the last one died despite being enrolled in study. This participant died only after one day of admission and without starting an anticoagulant or having an IVC filter inserted.

Conclusion: Trauma patients are at risk of thromboembolic episodes. Early insertion of an IVC filter along with prophylactic anticoagulation prevented the development of PE.

Keywords: IVC filters (inferior vena cava filters), PE (pulmonary embolism), DVT (deep venous thrombosis), Trauma

Introduction

In previous decades, venous thromboembolism (VTE) was described mainly as a complication of prolonged hospitalization after surgical interventions [1]. However, recent trials have shown a wide variety of risks of VTE in medical patients who were hospitalized with acute medical illnesses compared to those who were surgical patients [1]. Furthermore, epidemiologic research has demonstrated that between one quarter and one half of all clinically recognized symptomatic VTEs occur in individuals who are neither hospitalized nor recovering from a major illness [1,2]. This increases the recognition of at risk peoples and challenges specialists to carefully examine influencing factors for VTE to recognize high-risk patients for prophylaxis. The identified factors that are sufficient by themselves to consider VTE prophylaxis include major surgeries, multiple traumas, hip fractures, or lower extremity paralysis [1,3]. However, the increase in the utilization of prophylaxis measures of VTE, deep venous thrombosis (DVT), and pulmonary embolisms (PEs) are still prevailing health problems [3-5].

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Trauma patients are at risk of developing (VTE) such as DVT and PE [6]. The reports of VTE among trauma patients reflected that PE is the third leading cause of death. Furthermore, patients improving from trauma have the peak rate of VTE compare to other subgroups [5]. In addition, trauma is considered one of the influencing factors for (PEs). PEs following development of DVT is one of the most preventable causes of death in hospitalized patients [7].

The recent guidelines recommend low-molecular-weight heparin therapy to prevent embolisms [8], but trauma causes some patients to be at risk of excess bleeding. Evidence is divided on the role of prophylactic inferior vena cava (IVC) filters in preventing embolisms [6]. Some studies have suggested that IVC filters decrease the risk of PEs in various patient populations, including critically ill and trauma patients [6,9-12].

The level of evidence that supports the effectiveness of IVC filters in preventing PEs is low, but it supports the association of filter insertion with a low rate of PEs among trauma patients [6]. Furthermore, the harms associated with using the filter is unclear [6]. Despite improvements in diagnostic techniques and anticoagulation drugs, patients continue to face the thromboembolic problem. Sometimes, the use of an anticoagulant is contraindicated, results in more risks, or fails to treat or protect against embolisms. These cases are managed with IVC filters; however, the use of IVC filters in decreasing DVT and PE episodes is more effective than using anticoagulation alone [13]. Thus, this study performs an observational study that compare the effectiveness of the prophylactic insertion of IVC filters in patients with femur or pelvic fractures; its aim is to determine if the IVC filters insertion combined with prophylactic anticoagulation is superior to prophylactic anticoagulation in preventing thromboembolic events in trauma patients.

Material and Methods

Study design

This study is an observational comparative study that aims at assessing the effectiveness of IVC filters in trauma patients. The enrolled patients were observed for the development of PEs and to compare those who had IVC filters inserted and those who didn't have IVC filters inserted, in relation to the development of PEs.

Study area and time

Between April 2015 and October 2016, 36 trauma patients were assessed in an ICU at Care National Hospital in Riyadh, Saudi Arabia.

The study was conducted during 14 months, starting with the ethical approval time, and then moving to the data collection frame, followed by conducting the statistical analysis, writing the manuscript, and ending with submission.

Study population and patient eligibility

The patients were admitted to an ICU with pelvic or femur fractures. Thirty- six patients were admitted to the ICU at Care National Hospital in Riyadh, Saudi Arabia, with pelvic or femur fractures.

Inclusion criteria

Adult trauma patients who admitted to the ICU with lower

limbs, long bone fractures, or pelvic fractures were included in this study.

Exclusion criteria

- Patient has an allergy or sensitivity to device materials or contrast medium.
- Patient refuses a blood transfusion; has a bleeding disorder, has an existing IVC filter.
- Patient has anatomy that would prevent safe filter placement.

Sampling and sample size

The patients were selected using the convenience sampling technique. The ICU admissions during a specified period were considered to be the sample in this study. The sample was 36 patients. Three patients died during the study, but only one died of a major PE, and this patient had started anticoagulation but had no IVC filters inserted; the second patient died from septic shock and severe ARDS; and the last one died despite being enrolled in the study. This participant died only after one day of admission and without starting an anticoagulant or having an IVC filter inserted.

Data Management

The data were collected from patients and treated physicians. The process of data collection was conducted during the specified period and included patients' demographics, such as age, sex, type of fracture, the use of an IVF, and the outcome related to a PE or anticoagulant use.

IVFs were inserted by the ICU physician in patients with fractures to prevent PEs. All patient data are recorded on a computerized patients charting system. Patients with fractures were recognized according to the type of fracture (pelvic, femur, or long bone). Patients were assessed for either having a PE or using an anticoagulant.

Statistical Analysis

Data were analysed as a descriptive analysis using the frequency, percentage, or mean and standard deviation. Patients were categorized as either having IVF or not. The main outcomes of this study included the occurrence of an embolism (PE) or death.

Comparisons of proportions were done using chi-square tests for the groups. All reported *P* values are 2-sided and were not adjusted for multiple comparisons. Furthermore, *P*<0.05 was considered to be statistically significant. The analysis was performed using SPSS version 22.

Ethical consideration

Patient information was kept confidential throughout the study, and anonymous numbering was used on the data collection sheets.

Results

A total of 36 patients were admitted to the ICU during/ prior to the period of the study. The patients' demographics are summarized in Tables 1 and 2.

Thirty patients had IVC filters (83.3%), and none of them

Variable	Parameters	
	Age (years)	Mean
SD		±10
Sex	Male	36 (100%)
	Female	0 (00%)

Table 1: Demographic characteristics of patients with trauma at the intensive care unit at National Care Hospital in Riyadh, Saudi Arabia

Variable	Frequency (n=36)	Percent %	
Mode of trauma	RTA	30	83.3
	Gunshot	1	2.8
	FFH	5	13.9
Pelvic fractures	Yes	19	52.8
	No	17	47.2
Femur fractures	Yes	15	41.7
	No	21	58.3
Long bones fractures	Yes	15	41.7
	No	21	58.3
Combined fractures	Two fractures	10	27.8
	Three fractures	1	2.8
IVC filter use	Yes	30	83.3
	No	6	16.7
AC use	Yes	24	66.7
	No	12	33.3
AC and IVC filter use	Yes	21	58.3
	No	15	41.7
PE	Yes	2	5.6
	No	34	94.4
Death	Yes	3	8.3
	No	33	91.7

RTA= Road traffic accident
 FFH= Fall from height
 AC= Anticoagulant
 PE= Pulmonary embolism
 IVC= Inferior vena cava

Table 2: Clinical characteristics of patients with trauma at the intensive care unit at National Care Hospital in Riyadh, Saudi Arabia

were positive for a PE (p = 0.02). Among 24 patients using anticoagulants, a PE was only reported in 1 patient (4.2%; p=0.6), Table 3.

Three patients died during the study, but only one died of a major PE, and this patient had started anticoagulation but had no IVC filters inserted. The comparison of patients with IVC filter insertion related to death showed that only one patient in the IVC filter group died (3.3%; p=0.01). The use of anticoagulants had no significant effect on the occurrence of death; among the 24 patients who used anticoagulants, only 2 died (8.3%), Table 4.

Discussion

The attempts to prevent PE by using IVC filters have been researched since 1893. IVC filters have been available for 24 years, and currently, many types are commercially used in the United States [14]. Patients continue to face VTEs despite developments in diagnostic imaging and anticoagulation routines. In specific cases, usual medical treatment for a VTE is not allowed, leads to complications, or fails to adequately prevent patients from embolic events. These patients are cured with the insertion of

Variable	PE N (%)	No PE N (%)	P-value
IVC filter	Yes	0(00%)	0.02*
	No	2 (33.3%)	
Anticoagulant	Yes	1 (4.2%)	0.60
	No	1 (8.3%)	
IVC filter & anticoagulant	Yes	0(00%)	0.1
	No	2(13.3%)	

* Significant
 IVC= Inferior vena cava
 FFH= Fall from height
 PE= Pulmonary embolism

Table 3: Association between patients with IVC filters and patients with no IVC filters in relation to the development of PE and the association between patients with AC and patients without AC in relation to the development of PE

Variable	Survivors N (%)	Death N (%)	p-value
IVC filter	Yes	29 (96.7%)	0.01*
	No	4 (66.7%)	
Anticoagulant	Yes	22 (91.7%)	1.0
	No	11 (91.7%)	
IVC filter & anticoagulant	Yes	20 (95.2%)	0.6
	No	13 (86.7%)	

* Significant
 IVC= Inferior vena cava
 FFH= Fall from height
 PE= Pulmonary embolism

Table 4: Association between patients with IVC filters and patients with no IVC filters in relation to death and the association between patients with AC and patients without AC in relation to death

IVC filters. Even though it appears that IVC filters decrease long-term PE rates, there might be a higher associated rate of IVC thrombosis and lower-limb DVTs than with using anticoagulation alone [13].

The use of prophylactic IVC filters in trauma patients was common. This study reflected that approximately 83.3% of all trauma patients received an IVC filters, with 21 (58.3%) of them having both IVC filters and anticoagulants for prophylaxis. The utilization of IVC filters for prophylactic increased over time. The previous report demonstrated lower levels of IVC filter utilization [11,15,16]. This study demonstrated that 24 (66.7%) of the patients were on anticoagulants.

This study showed that 2 (5.6%) of the patients had PE and that 3 (8.3%) of patients did not survive (the causes of death include; one having PE, and one suffering from septic shock and severe ARDS, and the third dying before starting an anticoagulant or an IVC filter was inserted). These findings are similar to previous studies, which reflected a drop in the rate of PE after IVC filter utilization; one study reported a decrease in the PE rate from 4.8% to 1.6% [15], another study reported that trauma patients with IVC filter made up 51% of patient population without complications. Other previous studies showed a drop in PE incidence after IVC filter utilization [16-18].

Recently, IVC filters have been used instead of surgical IVC interruption. These IVC filters were permanently inserted and then expanded to be retrievable [16,19]. IVC filters were mainly used for trauma patients who experienced an existing VTE and for whom anticoagulation was not safe. IVC filters were later used

as prophylactics for patients with a high risk for VTE; such as those suffering from major trauma [19]. A survey on trauma was published in 1997 and reflected the anticipated increase use of IVCs [20]. A number of studies using data on IVCs between 2002 and 2017 reflected the overall increase in the use of prophylactic IVCs [15,17,21,22]. There were also significant differences in the utilization of prophylactic IVCs among different trauma patients [19]. One of these studies, reflected that the rate of prophylactic IVC filters insertion ranged from zero to 13 per 100 patients in high risk patients [19].

The influencing factors associated with the usage of prophylactic IVC filters, including the severity and pattern of trauma, are considered to be risk factors for PE. Remarkably, 8.3% of the patients died; one of them died from major PE, and this patient had started anticoagulation but had no IVC filters inserted. The use of anticoagulants had no significant effect on the occurrence of death, among the 24 patients who were on anticoagulants. However, some studies reported a decrease in the rate of the effectiveness of IVC filter utilization. One study reported a drop in the use of IVCs from 2.8% to 1.6% [16]. Another study showed that using IVCs increases the risks of DVT [23].

Many limitations have been reported; including the approach to data collection and; no measurements taken for hospital stays. Males were dominant in this group of patients, which is arbitrary and subject to question. Further studies may need to be conducted among different genders. Other limitations includes a small sample size, as only 36 patients were included; another is the non-random selection of the study group participants and that the study was conducted in one hospital. This means that we only can reflect internal validation of the study's findings. Nonetheless, this study has several strengths. This study is the first descriptive study in Saudi Arabia about IVC filters and the comparison of IVC filters and, anticoagulants and the use of both on trauma patients.

Conclusion

Trauma patients with lower-limb long bone or pelvic fractures are at a high risk of thromboembolic events, including major PEs. The early insertion of IVC filters in addition to prophylactic anticoagulation use prevented the development of PE. These findings need to be confirmed in a large scale randomized trial.

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