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#### REFERÊNCIA

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# Vena cava filters: a decade of experience in a level I trauma center

# Filtro de veia cava: uma década de experiência em um centro de trauma nível I

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#### ABSTRACT

**Objective**: To evaluate the data on the use of vena cava filter in the Division of Trauma, UCSD Medical Center - San Diego, CA / USA. **Methods**: A descriptive study was conducted at the Division of Trauma to evaluate the cumulated experience and the therapeutic approach in patients attended by the staff of the Division of Trauma and submitted to placement of a vena cava filter as a method of prevention or treatment of Pulmonary Thromboembolism (PTE) from January 1999 to December 2008. **Results**: The study comprised 512 patients, mostly males (73%). As to the cause, automobile accident injuries predominated, followed by injuries caused by falls. The male / female ratio was 3:1. The most affected age group was the one between 21 to 40 years, representing 36% of patients. The percentage of prophylactic vena cava filters was 82%, whilst 18% had treatment purposes. Head trauma was the main cause for the indication of prophylactic filters followed by spinal cord trauma. The rate of pos-filter deep vein thrombosis (DVT) was 11%. **Conclusion**: In the presence of contraindications to the use of anticoagulants in patients who suffered severe trauma, the inferior vena cava filters have proven to be an effective and safe option. However, one should apply rigorous clinical judgment to all indications, even after the advent of retrievable filters.

Key words: Wounds and injuries. Therapeutic approaches. Vena cava filters. Vena cava filters / effects. Vena cava filters / use.

#### INTRODUCTION

Traumatic injuries are among the leading causes of morbidity and mortality in contemporary societies according to the World Health Organization – WHO<sup>1</sup>.

The Medical Center at the University of California, San Diego (UCSD) has been a pioneer and a center of reference in the specialized care in trauma, with the designation of Level I Trauma Center by the Committee on Trauma of the American College of Surgeons since 1984.

The Trauma Center has three resuscitation beds and an exclusive surgical center located in the area adjacent to the Surgical Intensive Care Unit (SICU), the blood bank and the clinical laboratory. Patients are assisted by a specialized multidisciplinary team under the leadership of a general surgeon expert in trauma surgery, trauma specialized nurses, neurosurgeons, orthopedic surgeons and plastic surgeons. All aspects of specialized trauma care are provided to each patient in this unit. As part of the multidisciplinary approach, patients are submitted to the prophylaxis of deep vein thrombosis (DVT) / Pulmonary Thromboembolism (PTE) in accordance with established protocols and weekly tracking of thromboembolic disease by vascular ultrasound of the lower limbs<sup>2</sup>.

Thromboembolic disease remains an important cause of morbidity and mortality in trauma patients. In the U.S. the annual incidence of non-fatal PTE falls between 450,000 and 650,000 cases, with an estimated 50,000 to 200,000 deaths each year from PTE<sup>3</sup>.

Prophylaxis of DVT with unfractionated heparin (UFH), low molecular weight heparin (LMWH) and physical methods of intermittent compression of the limbs have been used in order to reduce the incidence of DVT and subsequently venous embolism<sup>4</sup>. The preferred method of prophylaxis of thromboembolic disease has been systemic anticoagulation<sup>5</sup>. In the particular case of multiple trauma patients there are often contraindications to this therapy due to risk of bleeding by the nature of acute traumatic injuries and the need for urgent surgical treatment.

Victims of severe trauma patients at high risk of thromboembolic complications (pelvic, spine, and lower extremities fractures, patients limited to the bed, spinal cord or brain injuries) and with contraindications to systemic anticoagulation (risk of bleeding, bleeding in the brain or

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spinal cord) has been the main target of the indications for placement of a vena cava filter<sup>6</sup>.

These indications have been expanded in recent years, especially with the advent of retrievable filters that can be percutaneously removed when the condition due to which they were inserted no longer exists<sup>7</sup>. While their use may have theoretical advantages<sup>8</sup>, there are no relevant data to shed light on the clinical efficacy or adverse effects.

This study aims to analyze the data on the use of vena cava filters in trauma patients treated at the UCSD Division of Trauma, San Diego, California, USA.

### METHODS

We performed an analysis of prospectively collected computerized records of patients treated between January 1999 and December 2008 in the Division of Trauma, Department of Surgery at UCSD.

All patients treated at the Trauma Unit undergoing vena cava filter placement were included. Data were collected using a table that included the following variables: date and time of trauma admission, age, gender, origin, mechanism of injury, characteristics of the lesions, associated injuries, type of treatment, hospital stay and referral after discharge.

Cases were classified into categories by etiology: ASS = Assault (with interpersonal violence), BIC = bicycle accidents (falls, collisions with other vehicles or run-overs, poles, walls, houses); FFH = falling from a height and impacts related to falls (including direct collision with furniture, plants, and internal and external elements in homes), FF = found fallen (without specifying the exact source of trauma), FAI = injuries from fire-arms (including legal interventions, armed robbery, self-inflicted injury, single or multiple lesions, incidental, anywhere in the body); SW =stab wounds; MOTO = motorcycle accidents (including collision with other motor vehicles, bicycles, poles, walls, houses and falls), AUTO = car accidents (including collision with other motor vehicles, bicycles, poles, walls, houses, excluding motorcycles) OBT = other blunt trauma, ORV = accidents with off-road-type vehicles; PED = accidents with pedestrians, TR = accidents with trains, trams or vehicles that travel on rails.

The analysis focused on all patients with permanent and retrievable vena cava filters and the variables associated with venous thrombosis. We analyzed data regarding the type of trauma, age, gender, Injury Severity Score (ISS), Revised Trauma Score (RTS) and the differences between the groups with prophylactic and therapeutic vena cava filters in relationship to mortality, overall or due to PTE.

Results were expressed as the average for the quantification of the distributions; the p-value <0.05 was used as statistical significance between groups.

#### RESULTS

The study comprised 512 patients (Figure 1) who underwent placement of a vena cava filter, especially males (73%). The age group with the highest incidence was between 21 and 40 years, comprising 36% of the entire population in the ten-year period studied.

The average age was 44 years (range 13 to 95). As for the cause of trauma, car accident predominated (31%), followed by fall from height (23%).

The average hospital stay was 25 days. The average ISS was 25.7 and the mean RTS was 7.2. Spinal cord injuries were the most significant in this patient group.

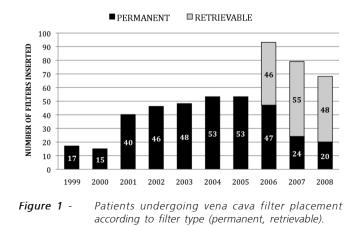
All patients who underwent placement of a vena cava filter had contraindications to anticoagulation.

The percentage of prophylactic filter placement (without previous DVT documented at the time of placement + contraindication to anticoagulation or treatment failure) was 82 (n = 420 – Figure 2). Head trauma was the main indication for prophylactic vena cava filter (254 cases = 60.5%), followed by the spinal cord trauma (74 cases = 17.6%) of severe multiple trauma with a high risk for DVT due to pelvic and / or long bones fractures in the lower limbs (LL) with inability to ambulate (65 cases = 15.5%) and thoracoabdominal injuries or by continuous use of oral anticoagulants (heart disease) that required emergency surgery (27 cases = 6 4%). There were 27 deaths in this group of patients (6.42%), only one death reported by PTE (0.23%) and confirmed by autopsy.

The prophylactic filters were followed by DVT in 43 cases (10%) in an average time interval of 14 days (ranging from 1 to 106) after placement of the filter, with two deaths in this subgroup of patients (Figure 3).

The therapeutic filters (with prior documented DVT or PTE + contraindication to anticoagulation or treatment failure) were indicated in 18% of cases (n = 92), with eight deaths in this group (8.7%). There were no deaths related to PTE in this patient group.

There was a steady increase in the use of vena cava filters since 2001, a stabilization in 2004/2005 and a peak in 2006 following the availability of retrievable filters.



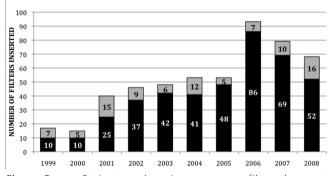
There was decrease in the use of such devices in 2007 and 2008, though.

There was no statistically significant differences with regard to gender, age, ethnicity, origin, length of hospital stay, mechanism of injury, type of injury, associated lesions and severity index between the groups with prophylactic and therapeutic filters.

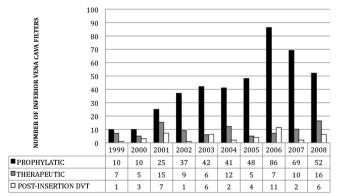
## DISCUSSION

The venous thromboembolic disease, including DVT and PTE, are common complications and important causes of morbidity and mortality in trauma victims who are recovering from serious injury. This population has an increased risk for venous thromboembolism, particularly in patients with lower limb or pelvic fractures, with an incidence of around 58% for distal DVT and 18% for proximal DVT in the absence of prophylactic measures<sup>9,10</sup>; half the patients who experience proximal DVT will develop pulmonary embolic episodes<sup>11,12</sup>. The risk ratio<sup>13</sup> correlates with associated factors such as age, type of trauma and its severity<sup>14,15</sup>.

■ THERAPEUTIC ■ PROPHYLATIC



*Figure 2* - Patients undergoing vena cava filter placement according to type of indication (therapeutic, prophylactic).



*Figure 3* - Patients undergoing vena cava filter placement according to type of indication (prophylactic, therapeutic) and the occurrence of DVT after placement of the device.

Guidelines promulgated by the Eastern Association for the Surgery of Trauma (EAST) and Brain Trauma Foundation suggest that patients who suffered severe trauma with intracranial hemorrhage, ocular lesions associated with bleeding, intra-abdominal solid organ injuries, pelvic fractures or retroperitoneal hematoma requiring transfusion would be at risk of serious bleeding complications for up to 5 to 10 days after the accident<sup>16</sup>.

Due to the acute traumatic nature of these lesions, there are often immediate and medium term contraindications to prophylaxis and anticoagulation medication because of potential bleeding complications (22% of trauma patients)<sup>17</sup>. Mechanical protection offered by prophylactic intracaval filter devices (cava filter) would be theoretically indicated in these cases<sup>18</sup>.

Unfortunately, the search for information Offered by controlled trials is hampered by methodological flaws or low statistical "power" of published studies, showing a gap that prevents meaningful conclusions about the effectiveness of prophylactic filters to prevent pulmonary embolism<sup>19,20</sup>.

EAST recommends considering the inclusion of vena cava filters in patients without documented DVT who cannot receive pharmacological prophylaxis. However, there is a significant variation in the indication of these devices, as shown in a retrospective review of 21 U.S. trauma centers. It is also observed that vena cava filters are indicated in a percentage twice as high in trauma units receiving a low volume of patients.

Vena cava filters are effective in preventing PTE in patients with documented DVT and contraindication to anticoagulation (therapeutic indication). Nonetheless, there are no controlled studies regarding the effectiveness and safety of these devices as a prophylactic measure in preventing PTE in patients at risk of DVT and major bleeding complications and, as of today, the ideal type of prophylaxis in these cases remains unknown. There are also studies showing a higher incidence of risk for development of DVT in patients with intracaval filter devices, which can result in long-term complications such as chronic venous insufficiency and ulceration<sup>21</sup>.

Most patients undergoing placement of vena cava filters in this study had no evidence of previous DVT (82% of prophylactic filters versus 18% of therapeutic ones). There was a definite trend in the use of retrievable filters from 2006 on, although many of these filters remain in situ on a permanent basis, similar to that found in other publications<sup>22</sup>.

We found an incidence of post-filter DVT of 10.7%, occurring in an average time of 14 days after insertion, showing correlation with results published in other studies (4% to 30%) and lower than the rate of DVT in historical groups of patients in trauma victims at high risk for DVT (67%) in the absence of prophylaxis<sup>23</sup>. We could not establish whether the DVT after filter placement led to a change in blood flow with a tendency to proximal thrombosis, but the device has fulfilled its purpose efficiently, because there was only one death related to PTE (0.19% of total cases, 0.24% when considering only cases with

prophylactic filter indication). In previous studies this rate varied between 1.2 and 4.6%<sup>24,25</sup>.

It should be emphasized that in this study systematic examinations of Doppler vascular ultrasound were weekly performed for screening and follow-up of DVT in lower limbs since admission.

In future controlled studies it would be interesting to consider the comparison between groups of high risk patients undergoing only vascular ultrasound monitoring for early diagnosis of DVT and patients undergoing placement of prophylactic vena cava filters, to evaluate the best strategy for PTE prophylaxis in patients suffering severe trauma and having contraindication to pharmacological prophylaxis. The adjusted mortality rate for decision analysis attributed to PTE in this specific population of patients appear to be small (0.22% without filter x 0.13% with filter)<sup>26</sup>. This approach was suggested by the group at the University of Calgary in Canada, which showed a better performance in the analysis of positive outcomes and lower costs associated with the use of serial Doppler ultrasound compared with prophylactic vena cava filter insertion. However, the results need to be interpreted within the context of the limitations related to vascular Doppler ultrasound screening for DVT in this patient group, the study design (cohort), as well as the reliance in economic analysis of an intensive care unit regional center in Canada, which limits generalizations.

This study did not aim to analyze data on the removal of retrievable devices implanted. The management in such cases is the monitoring of all patients in the Division of Trauma, and referral of those with indication for removal of vena cava filters to the Interventional Radiology Unit at the hospital. A previous analysis showed that only 30% of the filters are removed in a period of six months after placement.

The advent of retrievable vena cava filters provided an increase in their use, especially in patients at high risk for DVT/PTE for treatment failure, complications, or contraindication to the use of anticoagulant drugs. However, the removal of these temporary devices is less than expected, exposing patients to the same risks of potential complications of intracavitary permanent devices. A recent study in 21 institutions, conducted by the American Association for Surgery of Trauma (AAST), showed that only 22% of intracaval temporary filters were removed, a fact directly related to patient follow-up in a medical facility other than that in which the device was inserted. They concluded, therefore, that the service or sector of placement of the retrievable intracaval filter should be responsible for the patients' aftercare, in order to bring the rate of removal of these temporary devices to the theoretically desirable 87%<sup>22</sup>.

Motor vehicle accidents were the leading cause of injury cases recorded. Prophylactic vena cava filters (82% of cases) were used as a primary strategy in patients at high risk for thromboembolic complications and contraindications to anticoagulation drugs, especially in patients with brain and spinal cord trauma. There was only one death related to pulmonary embolism (0.19% of total cases). We observed a greater indication of prophylactic filters after the availability of retrievable filters.

Anticoagulants remain the mainstay of treatment in patients at high risk of DVT or pulmonary embolism. The main indication for the use of intracaval filtering devices is documented DVT with contraindications to anticoagulation.

In the absence of compelling evidence about the benefits of routine use of prophylactic vena cava filters, ACCP guidelines<sup>4</sup> remain valid. Careful clinical judgment should be applied for all indications, despite the low rates of adverse events of short and medium term, even after the advent of retrievable filters.

The use of systematic tests of vascular Doppler ultrasound for early screening and follow-up of thromboembolic disease in patients who suffered severe trauma should be encouraged.

In the presence of contraindications to the use of anticoagulants in patients who suffered severe trauma, inferior vena cava filters have proven to be an effective and safe option. However, one should exercise rigorous clinical judgment to all indications, even after the advent of retrievable filters.

#### RESUMO

**Objetivo:** Avaliar os dados relativos à utilização de filtro de veia cava na Divisão de Trauma do Centro Médico da UCSD – San Diego, CA/EUA. **Métodos:** Estudo descritivo realizado na Divisão de Trauma visando avaliar a experiência acumulada e a conduta terapêutica nos doentes atendidos pela equipe da Divisão de Trauma e submetidos à colocação de filtro de veia cava como método de prevenção ou tratamento do TEP no período de janeiro de 1999 a dezembro de 2008. **Resultados:** O estudo compreendeu 512 doentes, destacando-se o sexo masculino (73%). Quanto à causa do traumatismo predominou o acidente automobilístico, seguido por lesões provocadas por quedas. A relação homem/mulher foi 3:1. A faixa etária mais atingida foi 21 a 40 anos, representando 36% dos doentes. O percentual de filtros de cava profiláticos foi de 82% contra 18% de filtros terapêuticos. O traumatismo craniano foi a principal causa para indicação de filtros profiláticos seguido dos traumas raquimedulares. O índice de TVP pós-filtro foi 11%. **Conclusão:** Na presença de contraindicação ao uso de anticoagulantes em doentes vítimas de trauma grave, os filtros de veia cava inferior demonstraram ser uma opção efetiva e segura. Entretanto, deve-se aplicar rigor ao julgamento clínico para todas as indicações, mesmo após o advento de filtros "recuperáveis".

Descritores: Ferimentos e lesões. Condutas terapêuticas. Filtros de veia cava. Filtros de veia cava/efeitos adversos. Filtros de veia cava/utilização.

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