ARE THERE ANY RISK FACTORS FOR DEVELOPING COMPLICATIONS WITH THE USE OF RETRIEVABLE VENA CAVA FILTERS IN ORTHOPAEDIC SURGERY?

¿EXISTEN FACTORES DE RIESGO PARA DESARROLLAR COMPLICACIONES CON EL USO DE FILTROS DE VENA CAVA REMOVIBLES EN CIRUGÍAS ORTOPÉDICAS?

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Abstract:

Background: Thromboprophylaxis may be insufficient to prevent thromboembolic events in high risk patients after orthopaedic procedures. In this scenario, a retrievable vena cava filter (VCF) could be considered as an alternative, although it's use remains controversial. Aim: To estimate mortality, mechanical and hematological complications associated with the use of retrievable VCFs in orthopaedic surgery Methods: Retrospective cohort of patients with history of thromboembolic (TED) disease who underwent orthopaedic surgery and a retrievable VCF was placed, between 2006-2014 at Hospital Italiano de Buenos Aires. Permanent filters were excluded. The main outcomes were filter's mechanical complications, hematologic complications (TED recurrence, post-thrombotic syndrome and major bleeding) and death. To estimate association with risk factors, we subclassified surgeries into 5 groups: 1, arthroplasty/non-arthroplasty; 2, primary/revision; 3, elective/urgent; 4, oncologic/non-oncologic; 5, preoperative/postoperative filter. Results: Sixty eight patients were included, of those 31 presented a complication. Mechanical complications were 16% and required a filter revision. Sixty-four percent of the revised VCFs developed a mechanical failure and could not be retrieved. Overall prevalence of TED recurrence, post-thrombotic syndrome and hemorrhage was 33%, 15% and 4.5%, respectively. Spinal surgeries were a risk factor for developing TED recurrences. The mortality rate was 28% and death related with TED recurrence 4%. Conclusions: Orthopaedic procedures had a high risk of mechanical and hematologic complications after using a retrievable VCF. However, mortality was low due to these complications.

Keywords: retrievable vena cava filter; thromboembolic disease; orthopedic surgery; deep vein thrombosis; pulmonary embolism

Resumen:

Introducción: En pacientes sometidos a cirugía ortopédica y con antecedente de Enfermedad tromboembolica, la profilaxis común suele ser insuficiente para prevenir eventos tromboembólicos. Los filtros de vena cava (FVC) removibles pueden considerarse una alternativa. Objetivos: Estimar la tasa de complicaciones hematológicas, mecánicas y muertes asociadas al uso de FVC removibles en cirugía ortopédica. Métodos: Se diseñó una cohorte retrospectiva de pacientes con historia previa de Enfermedad tromboembolica (ETE) sometidos a procedimientos ortopédicos que requirieron FVC removible, entre el 2006-2014 en el servicio de ortopedia del Hospital Italiano de Buenos Aires. Se definió complicación asociada al FVC a las complicaciones mecánicas, hematológicas (recurrencia de ETE, síndrome postrombotico y sangrado mayor) y muerte. Para estimar la asociación con factores de riesgo, subclasificamos a las cirugías en 5 grupos: 1, artroplastia/no artroplastia; 2, primaria/revisión; 3, electiva/urgente; 4, oncológica/no oncológica; 5, filtro pre/postoperatorio. Resultados: Se incluyeron 68 pacientes, de los cuales 31 presentaron algún tipo de complicación. Las complicaciones mecánicas ostentaron un 16%, precisando de una revisión del filtro. 64% de los filtros revisados fallaron mecánicamente y no pudieron ser extraídos. Las tasas de recurrencia de ETE, síndrome postrombotico y sangrado mayor fueron del 33%, 15% y 4.5%, respectivamente. Las cirugías espinales presentaron un mayor riesgo de recurrencia de ETE. La mortalidad global fue del 28% y 4% asociada a recurrencia de ETE. Conclusiones: Las cirugías ortopédicas exhibieron un riesgo elevado de complicaciones mecánicas y hematológicas luego de usar un FVC removible. Empero, la mortalidad debido a dichas complicaciones fue baja.

Palabras Clave: filtro de vena cava removible; enfermedad tromboembólica; cirugía ortopédica; trombosis venosa profunda; embolia pulmonar.

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Introduction

Thromboembolic disease (TED) is a frequent complication following orthopaedic procedures with a prevalence of almost 50% in the absence of any means of antithrombotic prophylaxis,[1] although modern rates are thought to be much lower.[2] In high-risk patients, such as those with previous or acute TED, coagulopathies, oncologic, high-grade congestive heart failure, atrial fibrillation or polytraumatized; common prophylaxes may be insufficient or contraindicated to prevent new thrombotic events.[3]

In this scenario, interfering with the venous flow with a vena cava filter (VCF) may be a reliable alternative. VCFs, introduced percutaneously, are metal alloy devices that mechanically trap fragmented thromboemboli from the deep leg veins in route to the pulmonary circulation. Given that most of the complication-related literature is composed of case reports, their exact complication rate is probably under-reported.[4] Nevertheless, it is widely believed that most filter's complications can be avoided by prompt removal: as time from implantation elapses, chances for a TED recurrence persist or may be even aggravated[5].

Consequently, retrievable filters are preferred over permanent ones nowadays, although there is a marked paucity of evidence describing their association with mechanical and hematologic complications in orthopaedic surgery[6-7]. The AAOS clinical practice guideline for preventing thromboembolic disease in patients undergoing elective hip and knee arthroplasty was unable to recommend for or against the use of filters because of inconclusive evidence[8]. This issue relies probably on the absence of neither formal clinical guidelines nor high quality evidence to support their indication. Seemingly, current reports of VCF use in orthopaedics are not updated since they mainly derive from an analysis of permanent filters[9-8].

To our knowledge, it remains controversial whether retrievable VCFs are actually beneficial for orthopaedic patients in whom pharmacological prophylaxis is contraindicated or deficient. Still, orthopedic procedures vary in complexity and certain surgeries are more likely to be associated with thrombogenesis, like arthroplasties;[10-11] we had hypothesized that patients undergoing arthroplasties, especially those performed urgently secondary to fractures, would have more overall complications related to the VCF than other kind of orthopaedic procedures.

Our aim was to estimate mortality and complications (mechanical and haematologic) of retrievable VCFs within orthopaedic surgery.

Methods

Design: Retrospective cohort of all consecutive adult patients with history of thromboembolic disease who underwent ortophedic surgery and received an inferior VCF between 2006 and 2014 at Italian Hospital of Buenos Aires. Patients were excluded if a permanent filter was placed, if they were operated by non-orthopaedic services, or if they were duplicate cases.

Indication for VCF was defined by the hematologist based on clinical criteria. General indications for transient filter use were: high-risk patients with contraindication to antithrombotic chemoprophylaxis and patients with suspicion of insufficient prophylaxis once already indicated[12]. In all cases a retrievable Günther Tulip® (Cook Medical, Bloomington, IN, USA) VCF was positioned at the infra-renal vena cava via the femoral vein. A trained angiographist was in charge of the procedure by using a standardized protocol. After accessing the femoral vein using real-time ultrasound, a 5-French pigtail catheter (Angiodynamics, Queensbury, New York) was advanced over a standard guide wire under fluoroscopic control. Once at the proper location, the filter was advanced through a 12-French introducer sheath and then gently deployed. After placement, a co-adjuvant therapy with subcutaneous enoxaparin at a prophylactic dose was indicated if patients did not have a contraindication. After filter retrieval and without a consistent protocol, patients continued to receive chemoprophylaxis with either enoxaparin or switched to oral anticoagulation for undefined time.

This study was observational, and all diagnostic and therapeutic medical decisions reflected current medical practice. This study was approved by the ethics committee of the Italian Hospital of Buenos Aires.

Variables and definitions:

Main outcomes:

- Hematologic complications: TED recurrence, post-thrombotic syndrome and major bleeding. We defined TED recurrence as a new diagnosis of deep vein thrombosis, through Doppler ultrasound, at any anatomic level of the circulatory venous system or any pulmonary embolus detected by angiotomography after the filter was initially positioned. We registered the date of the thrombotic and/or embolic event. Post-thrombotic syndrome was identified whenever signs and symptoms of chronic venous insufficiency secondary to venous hypertension and valvular incompetence were evidenced[13]. Finally, major bleeding was appointed if hemorrhage of the surgical site caused hemodynamic instability or a hemoglobin decline of 2g/dL or more[14].
- Mechanical complications: Related to the placement or extraction of the filter. Filter malposition was defined when the tip of the filter was not at or near the level of the renal vein inflow. Defective filter deployment was described as an incomplete expansion into the inferior vena cava. Filter migration was considered when the filter shifted to another part of the inferior vena cava, to the heart or to the pulmonary outflow tract. Filter fracture is named to a so. VCF incorporation into the vessel wall was defined as an embedding into endothelium at any portion of the filter, usually diagnosed during the extraction attempt. Finally, filter tilting was defined when it flexed more than 15 degrees from midline. In case any mechanical complication was detected, the requirement of a filter angiographic revision was computed. In all cases, an extraction attempt of the filter was always indicated, following a standard protocol.
- Mortality: Censored at the end of the study on March 2016.

Follow-up was performed through medical electronic records to assess orthopedic complications, and both through medical electronic records and telephonic interview to assess mortality and hematological complications

Demographic data were obtained from IRVTD registry and variables related to surgery were retrieved from the electronic clinical records (ECR). We described the demographic characteristics of all patients including age, gender and major comorbidities. We classified surgeries into 5 subgroups: 1, arthroplasty or non-arthroplasty; 2, primary or revision; 3, elective or urgent; 4, oncologic or non-oncologic; 5, with pre o postoperative filter. We also distributed them by anatomical location. We considered a revision surgery as a reoperation performed to correct undesirable sequelae of a previous surgery, with or without an addition or removal of implant components[15]. We defined VCF as pre or postoperative filter and measured time from VCF placement to surgery.

Statistical methods:

Descriptive analysis for categorical variables are expressed as absolute number and percentage, and continuous variables as mean and standard deviation or median and interquartile range, according to the observed distribution. Comparisons between groups were performed with the chi-square test for categorical variables and the Mann–Whitney U test for continuous variables.

Time to filter retrieval and thromboembolic recurrence (DVT and/or PE) since VCF placement were calculated with the Kaplan–Meier estimator and median survival time was expressed with its 95% confidence interval.

A two-sided $P<0.05$ was considered significant for all analysis. Statistical analysis was performed using STATA 13.0.

Results

Participants

We computed 186 eligible subjects that received an inferior VCF between 2006 and 2014. Of them, we excluded 118 for having permanent filters, being operated by non-orthopaedic services and/or duplicate cases (Figure 1). Thus, we finally included 68 patients in whom a retrievable VCF was collocated with a

minimum follow-up of 90 days. All of them had a history of previous thromboembolic event with a retrievable VCF placed within two weeks (before or after) of an orthopaedic surgical procedure. Fifty-four patients (80%) had a history of acute or chronic DVT whereas 26 (39%) had been diagnosed with PE. Additionally, 6% (n=5) of patients had a previously diagnosed coagulopathy

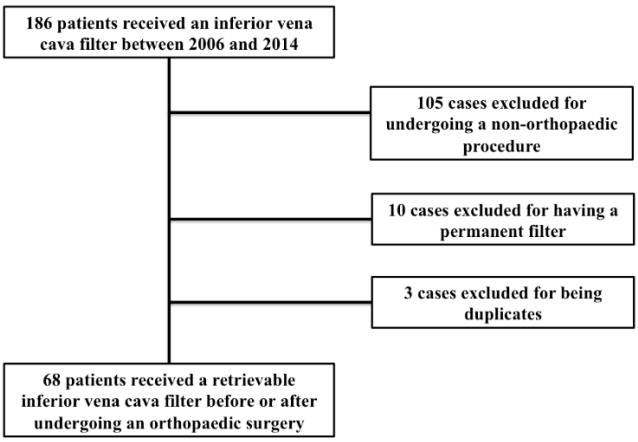

Figure 1. Flowchart depicting the selection criteria applied to the series.

The mean age was 72 (SD 16) years old and the 57% (39/68) were female. Median time of follow-up was 592 days (IQR: 116–1145).

The prevalence order of surgical procedures was as follows: 57% hip (39), 17% knee (12), 13% midshaft femur (9), 13% spine (9) and others (16). Sixty one percent (42) of the patients received vena cava filter preoperative and underwent their orthopaedic procedure at an average of 6 days (2-14) after VCF's insertion; those with postoperative filters (n=26) had undergone surgery at an average of 4 days (range, 1-6) before. In 45% of patients (n=31) non-arthroplasties were performed; the remnant 55% (n=37) belonged to hip or knee joint replacements. Additionally, 31% (n=21) of the total surgeries were elective whilst 69% (n=47) were done urgently. Sixty-five percent of patients (n=44) underwent primary procedures and 35% (n=24) consisted of revision surgeries. Finally, 30% (n=21) of cases involved oncologic patients; all of them diagnosed with stage IV disease.

Complications associated with VCF

Mechanical complications were seen in 11 (16%) cases: filter malpositioning observed in 9 cases (14.7%) and tilting in 3 (4.4%). All of them required a filter revision at the angiography operating room. Mean time to filter revision was 96 hours (range; 8-120 hours). Fourteen patients (21%) developed a mechanical failure, being filter incorporation into the vessel wall the main cause, seen in all but one case. The other filter had a two-fragment fracture during its extraction attempt; as one of the fragments could not be extracted; it was left 'in-situ' requiring implantation of an additional filter proximally. Of the mechanical failures, 64% of them had a revision previously.

Forty-seven patients had successful filter retrieval (Figure 2). The success rate estimate for filter removal was 69.12% (CI95%: 58.03–79.61) and the median time estimate to filter removal was 17.31 days (CI95%: 12.52–31.34). Patients who died before the first attempt to remove the filter were censored. Figure 2. Graph estimating time to filter retrieval, depicting a median time of 17days (IC95%: 13–31).

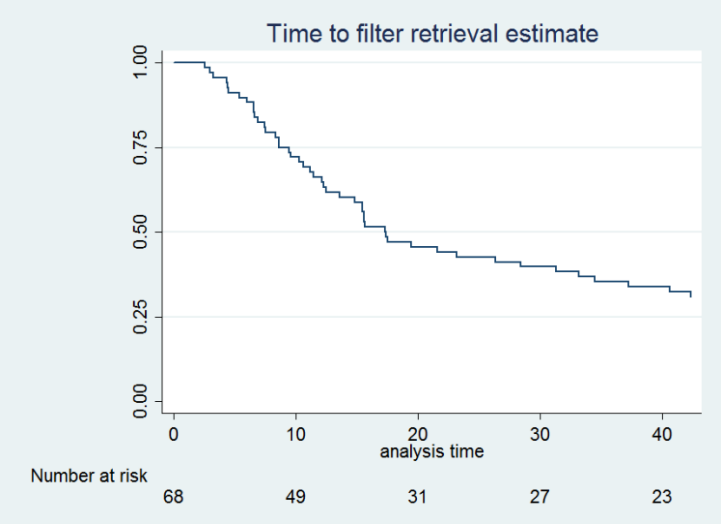

Figure 2.

Hematological complications were TED recurrence 30%, post-thrombotic syndrome 15% and major bleeding 4.5%. Twenty-one patients developed a TED recurrence: 22% (n=15) developed DVT, 8.82% (n=6) presented PE (Figure 3). Median time to TED recurrence was 40 days (IQR: 9– 173). Hematologic complications had not any statistically significant difference among the subgroups studied (Table 1**.** Hematologic complications among different groups and subgroups of patients). When comparing surgeries among different locations, spine fusions were a significant risk factor for developing at least one hematologic complication, especially TED recurrences. When estimating the hazard ratio specifically for TED recurrence adjusted by age and sex, we found no significant association either.

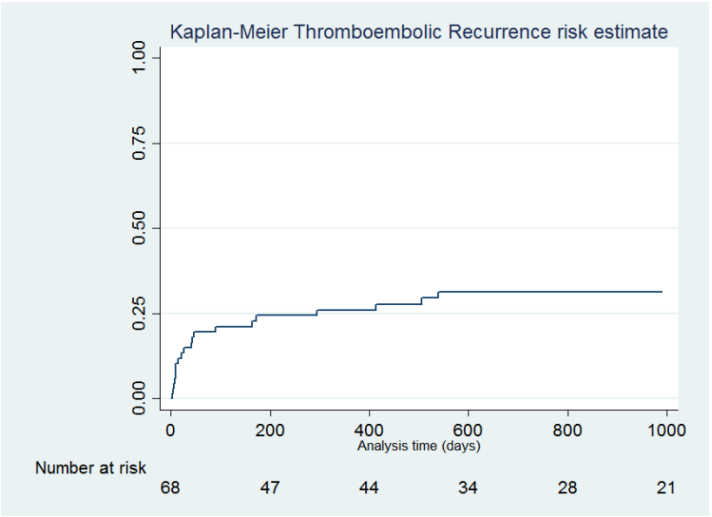

Figure 3.

Table 1: Hematologic complications among different groups and subgroups of patients

Variable	Total	Any complication	TED Recurrence	Post-thrombotic syndrome	Major bleeding
Non-arthroplasty	31	51.61 (16)	41.94 (13)	12.90 (4)	6.45 (2)
Arthroplasty	37	37.84 (14)	21.62 (8)	16.22 (6)	2.70 (1)
		p=0.25	p=0.07	p=0.70	p=0.45
Oncologic	21	57.14 (12)	38.10 (8)	19.05 (4)	14.29 (3)
Non-oncologic	47	38.30 (18)	27.66 (13)	12.77 (6)	-
		p=0.14	p=0.38	p=0.49	

Primary surgery	44	40.91 (18)	34.09 (14)	11.36 (5)	4.55 (2)
Revision surgery	24	50% (12)	29.17 (7)	20.83 (5)	4.17 (1)
		p=0.47	p=0.82	p=0.29	p=94
Elective surgery	21	47.62 (10)	33.33 (7)	14.29 (3)	4.76 (1)
Urgent surgery	47	42.55 (20)	29.79 (14)	14.89 (7)	4.26 (2)
		p=0.69	p=0.77	p=0.94	p=1
Preoperative filter	42	50 (21)	35.71(15)	14.29 (6)	7.14 (3)
Postoperative filter	26	34.62 (9)	23.08 (6)	15.38 (4)	-
		p=0.21	p=0.27	p=0.9	-
Spinal surgery	9	77.78 (7)	66.67 (6)	-	11.11 (1)
Arthroplasty	37	37.84 (14)	21.62 (8)	16.22 (6)	2.70 (1)
Rest of the surgeries	22	40.91 (9)	31.82 (7) p=0.03	18,18 (4)	4.55 (1)
		p=0.09		p=0.40	p=0.54

Values are presented as % (n)

TED: Thromboembolic disease.

Overall mortality was 28% (n=19), involving mostly end-stage oncologic patients (68% of the deceased). The main causes of death were unrelated neither to hematologic complications nor to filter collocation. Seven patients died because of multi-organ failure dysfunction syndrome due to sepsis; 3 due to acute renal failure; 2 because of acute respiratory failure with a negative helical angiotomography for embolism; 2 due to congestive heart failure and 1 patient secondary to a massive abdominal hemorrhage. In 4 cases the cause of death was not reported on the medical charts. Overall mortality due to a certified TED recurrence was 4%. Additionally, 52% of the deceased (10 out of 19 dead patients) had indication of a VCF because of a history embolic disease whereas on the remaining 48% it was indicated due to acute or chronic DVT.

Discussion

This retrospective cohort study provides an in-depth analysis of a group of high-risk patients who had an orthopaedic procedure within the placement of a single-branded retrievable VCF. Overall TED recurrence was 33%, similar to the reported risk for venographic DVT after joint arthroplasty or hip fracture in the absence of anticoagulation, that oscillates between 5% and 51%.[16-17] On the other hand, although overall mortality was 28%, only 4% of patients died due to a TED recurrence. The reported risk of symptomatic venous thromboembolism (VTE) can be as high as 28% with up to 10% of mortality when no thromboprophylaxis is used.[18-20] Therefore, our findings suggest that with the use of retrievable VCFs, an orthopaedic surgeon may not expect a reduction in the incidence of a new thromboembolic event, but indeed anticipate a decline in the death ratio attributed for TED.

Our study has several limitations. Its retrospective nature correlates with the boundaries of this study design. First, the sample size of the cohort resulted in a small number of patients included in the different groups and subgroups, restraining the production of more accurate statistical analyses such as a multiple regression investigation to categorize independent risk factors. Second, it was an observational with no control group; therefore a prospectively controlled trial remains necessary to corroborate our findings. Third, when evaluating mortality, the cause of death was assessed by the data registered on the digital medical charts and not by autopsy results. Although the circumstances leading to death were reviewed in detail in all cases, a post-mortem examination was not routinely performed due to lack of family consent in many cases, given the inclusion of several end-stage oncologic patients. Therefore, we believe our attributed mortality for TED should be considered of low estimate.

After analyzing 95 joint arthroplasties that received VCFs, Austin et al.[21] found that filters were effective at preventing fatal PE, although a relatively large number of recurrent DVT occurred, similar to our results. Another study observed an incidence of fatal PE of 4% with Greenfield permanent filters, recommending its use only in patients who have a thromboembolism with contraindicated anticoagulation, in those with complications secondary to therapeutic anticoagulation and those who are exceptionally at a high-risk for

thromboembolism. Golueke et al.[22] reported a similar mortality (4.6%) in 21 total joint replacements that received a prophylactic preoperative permanent filter.

Thirty percent of our series consisted of oncologic patients. Additionally, of the 19 dead patients, almost 70% were oncologic. It has been shown that the sole presence of VTE in an otherwise healthy patient should increase surveillance for detecting malignancies.[23] Oncologic patients definitely have a higher predisposition for thromboembolic events due to multiple causes: extrinsic vascular compression, tumor vascular infiltration, hypercoagulability induced by cancer-related cytokines, and pro-thrombotic chemo and radiotherapies.[24-25] Mikhail et al.[26] determined that there was a low overall complication rate after using retrievable VCFs in cancer patients. However, as retrievability was 2% and the mortality rate was almost 50% at 90 days, the authors concluded that end-stage patients might not benefit from the use of such filters. Conversely, when examining a group of patients with metastatic pathologic fracture of the lower extremity, a retrospective study evidenced that patients with retrievable VCFs obtained 8% of DVT and 0% of PE whereas patients that only received mechanical prophylaxis attained a 4.2% and 22% of DVT and PE, respectively.[27] Given the high mortality rate of the patients that developed PE, the authors strongly recommend the use of VCFs despite the morbidity associated with their insertion.

An inferior VCF's main purpose is to avoid new thromboembolic events in patients in whom anticoagulation has been contraindicated or remains insufficient. Prior studies have reported efficacious results in decreasing the risk of PE in high-risk trauma patients[28]. Nonetheless, as stated by a large randomized trial of patients with proximal DVT, the initial beneficial effect of VCFs for the prevention of PE seems to be counterbalanced by an excess of recurrent DVT at two years follow-up, without any difference in mortality[29].

When analyzing permanent filters' long-term effects, the PREPIC randomized controlled trial concluded that at eight years, vena cava filters reduced the risk of PE (hazard ratio 0.37) but increased that of DVT (hazard ratio 1.52) and had no effect on survival.[5] In order to methodically examine the evidence for the success of VCFs on preventing PE, only 2 studies[5,30] were able to meet the inclusion criteria in a level I systematic review of the literature carried out by Young et al.[31] They concluded that both studies lacked statistical power to detect a reduction in PE over shorter and more clinically significant time periods but proved that permanent filters were associated with an increased risk of long-term DVT. Like Young et al., we believe there is very limited evidence concerning VCF outcomes when used within their currently approved indications, especially of retrievable filters.

Several studies have reported on varied percentages of transient filter's mechanical complications and irretrievability when treating orthopaedic patients, especially in trauma cases[7,32-38]. Fullen et al.[30] reported that technical difficulties, largely mechanical, were more frequent in women and related to the small size of the jugular vein. Nonetheless, they found no filter migration, malposition nor perforation of the surrounding organs. Mechanical hindrances are reported to range from 0% to 6% whereas success in retrieving the filter varies from 21% to 64%. We believe that the true rate of filter retrieval is undervalued, since it can be influenced by the patient's clinical situation, the angiographist's experience and different institutional protocols[31]. We have described one of the highest ratios of mechanical complications. All of them were successfully revised within the short-term. Unfortunately, most of these revised filters (64%) failed later in obtaining a successful retrieval. Although there in some evidence that the permanent use of a retrievable VCF may be safe in the mid-term,[39] there is a high likelihood that the long-term settlement of the filter will mechanically stimulate the vessel's endothelium, activating the clotting cascade and enabling its definite incorporation into the wall.

A prospective observational cohort study of symptomatic thromboembolisms in 36388 orthopaedic patients determined an overall low occurrence of VTE (1%), with the highest incidence observed, in the presence of thromboprophylaxis, after internal fixation of pelvic fractures and total knee replacements; and the highest mortality seen after lower limb amputation and hemiarthroplasties due to hip fractures[40]. Moreover, when comparing 4001 surgical hip procedures, thromboembolic events and mortality were more frequent in THRs and hemiarthroplasties secondary to hip fractures than those performed electively due to degenerative hip disorders or revision surgeries. This concern coincides with our initial hypothesis of expecting more overall complications and mortality rates in patients undergoing arthroplasties, particularly those performed urgently. However, our findings suggest that no differences were found in overall TED recurrence, post-thrombotic syndrome or major bleeding, neither between arthroplasties and non-arthroplasties, nor between urgent and elective procedures. Given that VCFs are usually indicated in extremely high-risk individuals, we consider that our small number of patients is of low estimate to categorize specific risk factors.

We found a trend towards spinal surgeries being associated with TED recurrences. Spinal surgeries proved to have a higher risk of developing thromboembolic events than hip and knee arthroplasties in a previous study, since epidural anesthesia reduced the incidence of VTE when compared to general anesthesia[41]. Major surgical approaches during long general anesthesia periods, extensive spinal decortication and large anatomic dead space created during exposure derives in potential hemorrhagic complications and hematoma formation, which might be counterbalanced by the indication of a VCF.[42-43] The use of prophylactic VCFs as a standard protocol for high-risk patients undergoing major spinal instrumentations resulted in 18%

of patients with DVT and 3.7% of PE, without any related death in an 8-year period, decreasing the odds of thromboembolic events when compared with population controls[44]. Furthermore, patients that received permanent filters had significantly higher VTE incidence than those receiving retrievable ones. We consider that elderly patients, as the population described within this study, in the setting of long anesthesia-time, plays a major role in the settlement TED-related complications following spinal procedures[45-46].
In conclusion, orthopaedic procedures had a high risk of mechanical and hematologic complications after using a retrievable VCF in this series of complex patients. However, mortality was low due to these complications.

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