

Abstract Book 2017



2nd International RIETE Meeting (Seville, Spain)

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European Society
for Vascular Medicine



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Round Table 1

VTE Presentation in cancer

Upper extremity DVT in cancer patients

Dr. Vladimir Rosa

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Background

In cancer patients with deep vein thrombosis (DVT), the risk of developing pulmonary embolism (PE) during the course of anticoagulation has not been consistently analyzed.

Methods

We used the Registro Informatizado de pacientes con Enfermedad TromboEmbólica (**RIETE**) to identify which patients with active cancer and DVT are at an increased risk to develop acute PE during the course of anticoagulant therapy.

Results

As of August 2017, 7,490 cancer patients had been enrolled in RIETE with acute DVT. Of these, 6,461 (86%) had lower-extremity DVT, 393 (5.2%) non-catheter related upper-extremity DVT and 636 (8.5%) had catheter-related upper-extremity DVT. During the course of anticoagulation (median duration, 123 days), 143 patients had symptomatic PE, of whom 30 (21%) died of the PE. The results of the multivariable analyses will be presented during the meeting.

What to do next?

We must identify which cancer patients with DVT are at increased risk for PE and low risk for bleeding, and vice versa.

[illegible]

Round Table 1

VTE Presentation in cancer

Hidden cancer in patients with VTE

Dr. Luis Jara-Palomares

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Seville. Spain

Cancer patients are at an increased risk to develop venous thromboembolism (VTE), and VTE may also appear before the cancer has become symptomatic (thus leading to an early diagnosis of cancer) (1, 2).

The usefulness of a diagnostic workup for occult cancer in VTE patients is controversial, and current guidelines suggest that patients with unprovoked VTE should undergo a limited cancer screening including thorough medical history and physical examination, basic laboratory investigations and chest x-ray (3-7).

In a recent study using the **RIETE** registry database, we built a prognostic model to identify which patients with VTE were at an increased risk for subsequent cancer (8).

Our score helped to identify the most common sites of cancer according to gender and age subgroups. Moreover, this score has been externally validated but only after replacing one variable, and this implies a limitation (9).

External validation using all variables is necessary to let us identify a high-risk population in which extended screening may be useful.



Notes

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Round Table 1

VTE Presentation in cancer

Bleeding risk in patients with incidental PE

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Leiden. The Netherlands

Background

In recent years, physicians are increasingly confronted with 'incidental pulmonary embolism' (PE). The optimal management of incidental PE has not been addressed in clinical trials and available observational data are mostly limited to cancer-associated incidental PE, although guidelines recommend the same treatment as symptomatic PE. Notably, the risk of fatal bleeding in anticoagulated patients with cancer-associated incidental PE is much higher than the risk of fatal recurrent PE, which is a signal that some patients with incidental PE would benefit from continued anticoagulant treatment beyond the first three months of treatment in a risk-benefit ratio perspective, while anticoagulation in others may be best stopped at this time point. It is currently unknown how the optimal duration of treatment can be established for the individual patient.

Methods

In the current study, we aimed to assess the predictive accuracy of VTE-BLEED, a decision tool for predicting major bleeding during stable anticoagulation in patients with incidental PE included in the Registro Informatizado de Enfermedad TromboEmbólica (**RIETE**). The primary aim of this study was to assess the predictive value of VTE-BLEED for major bleeding after day 30 during active anticoagulant therapy for incidental PE. Secondary aims were to evaluate the predictive value of VTE-BLEED for recurrent VTE and overall mortality.

Results

Unpublished

Conclusions

Unpublished

What to do next?

If VTE-BLEED is able to identify patients with incidental PE at high risk of bleeding, a management trial should be performed to assess the safety of using VTE-BLEED to identify patients in whom anticoagulation should be stopped after three months of treatment.

Notes

[illegible]

Round Table 1

VTE Presentation in cancer

Superficial vein thrombosis

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The association between cancer and vein thrombosis is known since 19th century. Yet in last decades, the scientific community focused its interest toward the association between deep vein thrombosis (DVT) and cancer, probably because more frequently associated to pulmonary embolism and fatal pulmonary embolism. Therefore, superficial vein thrombosis (SVT) in cancer patients has been excluded from large randomized trials and little is known between site of SVT in cancer, modality of treatment and outcome of this kind of thrombosis in cancer patients. On the other hand, no guidelines are available concerning treatment regimens and duration of this disease.

The **RIETE** registry permits to explore the database concerning this association and to have an idea about the clinical approach toward this topic in real life. More than 73,000 patients with VTE are recruited in the **RIETE** database, and nearly 5600 patients with lower limb proximal DVT are available as nearly 805 with distal DVT as nearly 50 patients with SVT in cancer patients.

Clinical characteristics of cancer patients with SVT seems to be female gender and aged more than 70 years, with leg varicosities if compared with patients affected by DVT and cancer; few information are available concerning molecular thrombophilia and/or previous VTE in patients with SVT.

Fondaparinux or low molecular weight heparins are the common used drugs to treat SVT in cancer for a time less than 90 days usually. Their natural history seems to be worse if a SVT appeared: they had a higher rate of recurrences both, during and after discontinuation of anticoagulation.

Little is known about clinical characteristics of cancer patients with SVT. We observed the clinical history and management of nearly 50 patients with SVT and cancer and they seem to have a worse outcome. However data should be confirmed by large number of patients and need to be matched with other variables, such as thrombophilia and personal history of VTE.

Further information may be useful concerning migrans SVT, SVT in upper limbs, association with particular drug infusion, and association with venous catheters in superficial vein or in central vein as port-a-cath or PICC.

Notes

[illegible]

Round Table 1

VTE Presentation in cancer

Splanchnic vein thrombosis

Dr. Antonella Tufano

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Naples. Italy*

Background

Thrombosis in the portal venous system, which includes the mesenteric, splenic and portal veins, is collectively termed splanchnic vein thrombosis (SVT). Acute SVT may be symptomatic, but many episodes are detected incidentally in imaging studies performed for other indications, such as staging or assessing response to therapy in patients with cancer or liver diseases. The role of anticoagulant therapy in these patients is uncertain, given the absence of randomized trials on anticoagulation and the increased risk for bleeding in patients who often also have cirrhosis or cancer. Current guidelines from the American College of Chest Physicians (ACCP) recommend anticoagulant therapy in patients with symptomatic SVT (Grade 1B) and suggest no routine anticoagulation in those with incidentally found events (Grade 2C). However, supporting evidence for these recommendations is limited by the small size of the studies. We found only one study that specifically focused on patients with incidental SVT, showing that, after 2-year follow-up, outcome, in 177 patients with incidental SVT is similar to the outcome in 420 patients with symptomatic events, thus suggesting that similar treatment strategies should be applied.

Methods

Using the **RIETE** (Registro Informatizado de pacientes con Enfermedad TromboEmbólica) registry data, we compared the rates of venous thromboembolism recurrences and major bleeding during the course of anticoagulation in patients with symptomatic vs. incidental SVT.

Results

Our preliminary data provide evidence to confirm that patients with incidental SVT should be treated as those with symptomatic events.

Conclusions

However, our data suggest that caution should be exerted when starting anticoagulation in all patients with SVT, in particular in the presence of risk factors for bleeding.

What to do next?

Additional studies are needed to assess the most effective and safe therapy in this setting.

Notes

[illegible]

Round Table 2

The site of cancer

Pancreatic cancer

Dr. Corinne Frère

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Marseille. France

Background

Pancreatic cancer (PC) has been associated among the highest risk of thromboembolic events in cancer patients. This particularly high risk has been extensively and consistently documented.

Methods

We reviewed data from the literature to address the incidence and clinical outcomes of thromboembolic events in PC patients.

Results

Literature on arterial thromboembolic events in PC remains sparse. Reported venous thromboembolism (VTE) incidence varies widely in specific cohorts of PC, from 5% to 41 %, while rates are as high as 67% in postmortem series. Only a small proportion of PC patients were included in cancer patient studies investigating the risk of recurrent VTE or major bleeding during anticoagulant therapy.

However, scarce studies highlighted that VTE, and particularly early events, is associated with a significantly worse survival in PC patients. Hence, primary thromboprophylaxis (PTP) has been proposed as an adjuvant therapy in advanced PC. A recent meta-analysis of randomized controlled trials investigating the benefit and risk of PTP with low-molecular-weight heparins (LMWH) in ambulatory advanced PC patients receiving chemotherapy provided encouraging results, with crude VTE incidences of 2.1 and 11.2% in LMWH and in control groups respectively (risk ratio, 0.18; 95% CI, 0.083-0.39; $P < 0.0001$).

Conclusions

VTE is a frequent and serious complication in PC patient.

What to do next?

Given the paucity of specific data on the long-term clinical course of VTE in PC patients, it is important to better characterize the incidence and risk factors for recurrent VTE and major bleeding to further improve the management of VTE in this population of cancer patients.

Notes

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Round Table 2

The site of cancer

Lung cancer

Dr. Pedro Ruiz-Artacho

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Madrid. Spain

Background

Lung cancer is a common malignant disease worldwide and the leading cause of death from cancer.

The incidence of venous thromboembolism (VTE) in lung cancer patients is between 3-14% within 2 years. In clinical practice, the absolute number of VTE events is higher in lung cancer than in other cancer sites, because of the higher prevalence of lung cancer. However, there is scarce evidence on the clinical presentation of VTE, its management and outcomes in lung cancer patients.

Methods

We used data from **RIETE** (Registro Informatizado de pacientes con Enfermedad TromboEmbólica) to assess the clinical characteristics, management and outcomes of patients with lung cancer associated VTE. Also, we tried to identify variables associated with worse VTE-related outcomes during the course of anticoagulation.

Results

As of May 2017, 10,962 cancer patients were recruited, of whom 1725 (16%) had lung cancer. Of these, 70% initially presented with pulmonary embolism (PE). Most patients had no additional VTE risk factors, but had metastatic disease. The time elapsed since diagnosis was <3 months in 50%. Almost half of patients were not on cancer therapy. During anticoagulant therapy, the rate of VTE recurrences was more than twofold higher than the rate of major bleeding. Patients with deep vein thrombosis (DVT) had even more recurrences than those with PE. On multivariable analysis, we failed to find any variable associated with worse clinical VTE-related outcomes.

Conclusions

Lung cancer patients with VTE usually presented with PE, no other VTE risk factors but metastatic disease. These patients have more VTE recurrences than major bleeds. DVT patients had even more recurrences than PE patients.

What to do next?

Long-term outcomes of lung cancer patients treated with anticoagulants beyond 6 months versus defined treatment. To compare incidental versus symptomatic VTE, early (<3 months) versus lately VTE, and occult versus overt lung cancer associated VTE patients.

Notes

[illegible]

Round Table 2

The site of cancer

Breast cancer

Dr. Ángeles Blanco

Department of Internal Medicine

University Hospital Reina Sofía

Córdoba. Spain

Background

Tamoxifen and aromatase inhibitors remain a mainstay of the adjuvant hormonal treatment of all phases of estrogen receptor positive breast cancer. However, tamoxifen use increases the risk of symptomatic venous thromboembolism (VTE) in women with breast carcinoma by a factor of twofold to sevenfold, and the risk is much more pronounced when chemotherapy and tamoxifen are used combined. In addition, therapy with aromatase inhibitors is an independent risk factor for venous thromboembolism, because these drugs increase the incidence of VTE compared with the incidence among healthy women who do not receive any form of hormonal therapy. A higher risk for VTE during the first two years after tamoxifen exposure has been observed. In other study, tamoxifen use appeared to lead to a clustering of the VTE events at the start of therapy only in individuals with high VTE risk (obesity, advanced age and immobilization); although a persistent effect on VTE events for women with sustained exposure to tamoxifen over time was also noted. Data are lacking on the characteristics of VTE related to breast cancer hormonal therapy, the evolution during anticoagulant treatment and the efficacy of anticoagulation in combination with tamoxifen or aromatase inhibitors.

Methods

This work is our first approximation to VTE related with adjuvant hormonal therapy of breast cancer in order to obtain information about clinical presentations, risk factors, comorbidities and outcome during and after anticoagulation period. This information can help us to solve the dilemma of whether or not discontinuing hormonal treatment in the setting of VTE. We classified women with breast cancer included in **RIETE** Registry in three groups: women with tamoxifen, with aromatase inhibitors and women with breast cancer without hormonal adjuvant therapy.

Results

Unpublished

Conclusions

Unpublished

What to do next?

We need to keep on working to obtain tools that allow us to identify women who will benefit from maintaining hormonal adjuvant treatment for their breast cancer along with anticoagulation after developing a VTE.

Notes

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Round Table 2

The site of cancer

Colorectal cancer

Dr. Carme Font

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Background

Colorectal Cancer (CRC) is the second leading cause of cancer deaths in developed countries among men and women combined. On average, the lifetime risk of developing CRC is about 1 in 20 people, with 90% of cases occurring in patients older than 50 years old. The aim of the present study was to assess the epidemiological burden, risk factors and outcomes of patients with venous thromboembolism (VTE) associated to localized or metastatic CRC.

Methods

We retrospectively analyzed baseline clinical data and VTE-related outcomes of consecutive patients with VTE associated to metastatic or localized CRC from the Registro Informatizado de pacientes con Enfermedad TromboEmbólica (**RIETE**).

Results

Out of 71,929 VTE patients reported in the registry from March 2001 to July 2017, 1,555 (2.16%) had CRC (55% male; mean age 70 years old) with 673 cases (43.3%) with localized cancer and 882 patients (56.7%) with mCRC. During the course of anticoagulant therapy, patients with localized CRC received anticoagulation for longer periods and had lower rates of mortality, recurrent VTE and major bleeding compared to patients with mCRC. The results will be presented during the meeting.

Conclusions

CRC is a leading cause of cancer-associated VTE. Patients with localized (and potentially curable) CRC represents a large proportion of cases with specific concomitant VTE-risk factors and VTE-related clinical outcomes compared to patients with mCRC.

What to do next?

In depth analysis of concomitant VTE-risk factors and performance of currently available VTE predictive scores (Khorana, ONKOTEV, COMPASS) of VTE in patients with CRC.

Notes

[illegible]

Round Table 3

Long-term therapy of VTE

Lack of adherence to the guidelines: who and why

Dr. Dominique Farge-Bancel

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Paris. France

Background

Despite the publication of numerous national and international clinical practice guidelines, there are treatment gaps in the management of venous thromboembolism (VTE) in cancer on a global scale. Results of 14 studies with more than 20,000 patients worldwide are consistent with evidence of non-adherence to guidelines: 34% of patients with cancer did not receive long-term therapy (≥3 months) with low molecular weight heparin. ITAC-CME (www.itaccme.com), an international multidisciplinary group of clinicians and researchers established in 2013, is committed to disseminating relevant and peer-reviewed prophylaxis and treatment guidelines and education about VTE in cancer that are intended to help reduce a substantial economic burden on healthcare systems, improve the lives of patients worldwide and develop education.

Methods

With the publication of new studies and reports of non-guideline-based global adoption of direct oral anticoagulants (DOACs) for management of VTE in patients with cancer, ITAC-CME updated their 2013 consensus recommendations for treatment and prophylaxis of VTE. The revised guideline, published in *The Lancet Oncology* (October 2016; [http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(16\)30369-2/abstract...](http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(16)30369-2/abstract...)), provides a first guidance for appropriate use of DOACs in this patient population. To help clinicians adopt evidence-based care, ITAC-CME developed innovative, guideline-based knowledge dissemination strategies, including a free mobile application (available from the iOS App Store, Google Play and online at www.itaccme.com/en/practice-guidelines/guidelines-app), and an online continuing professional development program (CPD) that incorporates clinical practice assessments for Moore's Level 5 outcomes.

Results and last update

Data from more than 400 clinical practice assessments collected from physicians around the world revealed that 34% of physicians chose inappropriate anticoagulant treatment or treated patients for an inappropriate duration. Of inappropriate anticoagulants selected, 35% were DOACs. Additionally, 17% of physicians did not provide appropriate VTE prophylaxis for patients undergoing cancer-related surgery.

What to do next?

Education about evidence-based clinical practice guidelines and associated clinical trial data is required to help physicians make optimal anticoagulant treatment decisions for VTE treatment and prophylaxis, including appropriate choice of anticoagulant and treatment dosage and duration.

Notes

[illegible]

Round Table 3

Long-term therapy of VTE

Treatment beyond the sixth month

Dr. Pieter W. Kamphuisen

Department of Vascular Medicine

University Medical Center Groningen

Groningen, The Netherlands

Background

In patients with cancer-associated thrombosis (CAT), data on safety and efficacy of anticoagulant treatment beyond the sixth month is scarce. It is unclear whether anticoagulation should be prolonged after six months, despite recommendations from guidelines.

Methods

Patients from the **RIETE** registry who have active cancer and were treated with anticoagulants for ≥ 150 days will be analyzed to assess safety and efficacy of continuing or stopping anticoagulant treatment. To adjust for potential confounding by indication, we applied propensity-score matched (PSM) analysis to compare the rates of recurrent VTE, major bleeding and mortality beyond six months in patients treated for 180 ± 30 days and those treated > 210 days (prolonged treatment). Follow-up will start after cessation of treatment in the group treated for 180 ± 30 days, and after 180 days of treatment in the other group.

Results

Will be presented later in Seville.

Conclusions

The results from **RIETE** may give more evidence on the guidelines recommendations to prolong anticoagulant treatment beyond the sixth month in most patients with CAT.

What to do next?

After these results, the next step will be to identify patients that will benefit from prolonged anticoagulation.

[illegible]

Round Table 3

Long-term therapy of VTE

DOACs in RIETE

Dr. Manuel Monreal

Department of Internal Medicine

University Hospital Germans Trias i Pujol

Badalona, Barcelona. Spain

Background

The real-life use of the direct oral anticoagulants (DOACs) in cancer patients with venous thromboembolism (VTE) has not been previously reported.

Methods

We used the **RIETE** registry database to assess the patterns of use, but also the efficacy and safety of the DOACs in VTE patients with metastatic cancer, non-metastatic cancer and in those with no cancer.

Results

From January 2014 to September 2017, 26,365 patients with acute VTE have been recruited. Of these, 2,920 (11%) had metastatic cancer, 3,737 (14%) non-metastatic cancer and 19,708 (75%) had no cancer. During the first 7-10 days (initial therapy), 21,505 (82%) received low-molecular-weight heparin (LMWH), 1,081 (4.1%) unfractionated heparin, 633 (2.4%) fondaparinux, 2,905 (11%) rivaroxaban and 241 (0.9%) apixaban. For long-term therapy, 10,131 patients (47%) received vitamin K antagonists, 7,698 (35%) LMWH, 3,086 (14%) rivaroxaban, 651 (3.0%) apixaban, 139 (0.6%) dabigatran and 69 (0.3%) edoxaban. Data on the efficacy and safety will be presented during the meeting.

What to do next?

Further patients and data are needed to compare the efficacy and safety of the DOACs in different clinical scenarios. Particularly in patients with cancer, but also in other clinical scenarios associated with an increased risk for bleeding.

Notes

[illegible]

Round Table 3

Long-term therapy of VTE

The APICAT study

Dr. Isabelle Mahé

Department of Internal Medicine

Hôpital Louis Mourier

Colombes. France

Background

Most frequent encountered sites of cancer in patients with venous thromboembolism (VTE) are lung, colorectal, breast and prostate (1). For most of these sites the life expectancy has significantly improved (2), raising the question of extended treatment in those patients. Very few data are available in this field (3-5), from studies including any patient with cancer and VTE. The clinical course of VTE in patients with active cancer may differ according to the site of cancer.

Methods

We used data from an international registry of patients with venous thromboembolism (RIETE) to compare the risk of thrombosis recurrence or major bleeding and death while on anticoagulation in patients with of breast, prostate, colorectal, or lung cancer.

Results

As of September 2014, 3947 cancer patients were recruited, of whom 938 had breast (mean age 68y), 629 prostate (mean age 68y), 1189 colorectal (mean age 70y), and 1191 lung cancer (mean age 64y). Overall, 55% had metastatic disease (42%, 36%, 53%, and 72%, respectively). During the course of anticoagulant therapy (mean duration, 139 days), the rate of VTE recurrences was similar to the rate of major bleeding in patients with breast (5.6 [95% confidence interval (CI), 3.8-8.1] vs 4.1 [95% CI, 2.7-5.9] events per 100 patient-years) or colorectal cancer (10 [95% CI, 7.6-13] vs 12 [95% CI, 9.4-15] per 100 patient-years). However, in patients with prostate cancer, the rate of VTE recurrences was half the rate of major bleeding (6.9 [95% CI, 4.4-10] vs 13 [95% CI, 9.2-17] events per 100 patient-years), and in those with lung cancer, the rate of VTE recurrences was twofold higher than the rate of major bleeding (27 [95% CI, 22-23] vs 11 [95% CI, 8.6-15] per 100 patient-years). In patients with lung cancer, the rate of death was four to fivefold the rate of death associated with VTE and breast, prostate and colorectal cancer.

Conclusions

We observed that the risk of VTE recurrences and bleeding was higher in the first months of treatment. Guidelines suggest prescribing anticoagulants to patients with active cancer beyond 6 months irrespective of the site of cancer, due to the risk of recurrences. However, the profile of patients, comorbidities, and the thromboembolic risk associated with each cancer are highly different, such as the risk of bleeding. The benefit-to-risk ratio of anticoagulant therapy looks very different for treating VTE according to the site of cancer.

What to do next?

We aim at comparing a low-dose regimen of apixaban to a high-dose regimen of apixaban in extended treatment of VTE in patients completing 6 months of any anticoagulant treatment for treating a VTE event in a context of breast, colorectal or prostate cancer.

[illegible]

Round Table 3

Long-term therapy of VTE

TiCAT Study

Dr. Remedios Otero

Department of Pneumology

University Hospital Virgen del Rocío

Seville. Spain

Background

The main guidelines recommend the administration of low-molecular-weight heparin (LMWH) in patients with cancer-associated thrombosis (CAT). The National Comprehensive Cancer Network (NCCN) proposes anticoagulation treatment indefinitely in patients with active solid tumor or persistent risk factors. CATCH trial included the largest number of patients with CAT treated with tinzaparin versus vitamin K antagonists during 6 months and Daltecan study evaluated 185 patients with CAT receiving dalteparin for more of six months. Considering the limited data available on patients with CAT treatment beyond 6 months, TiCAT study evaluated the safety of long-term tinzaparin treatment in CAT.

Methods

We performed a study of the three public hospitals in Seville, open, single-arm study in adult patients with active cancer diagnosed with symptomatic or asymptomatic venous thromboembolism (VTE) treated with tinzaparin. Patients were initially followed by visits at one month and then every 3 months until death or end of study to evaluate clinical criteria of safety and efficacy.

Results

A total of 247 patients were recruited, with a crude incidence of major bleeding of 4.9% (12/247). The rate of clinically relevant bleeding during months 1–6 and 7–12, was 0.9% [95% confidence interval (95% CI) 0.5 to 1.6%] and 0.6% (95% CI 0.2 to 1.4%) ($p = 0.5$) per patient and month, respectively. Male gender showed greater risk for clinically relevant bleeding with a hazard ratio (HR) of 2.97 (95% CI 1.01 to 8.1; $p=0.02$). The incidence of VTE recurrence at months 1–6 and 7–12 was 4.5% (95% CI 2.2 to 7.8%) and 1.1% (95% CI 0.1 to 3.9%), respectively.

One patient died of Pulmonary Embolism and two because of major bleeding.

Conclusions

A favorable safety profile was demonstrated when tinzaparin was used for treatment beyond 6 months.

What to do next?

The appropriate time of anticoagulant treatment is a clinical challenge in CAT; we would need biomarkers that help us to take decisions.

Notes

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Round Table 4

Complications of therapy

Adherence to guidelines and outcome

Dr. David Jiménez

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University Hospital Ramón y Cajal
Madrid. Spain*

Background

Studies have not well defined the impact of adherence to published guidelines on the outcomes of patients with acute pulmonary embolism (PE) and active cancer.

We will perform a retrospective analysis of the data from the ongoing, international, multicenter, observational Registro Informatizado de pacientes con Enfermedad TromboEmbólica (**RIETE**) to evaluate whether patients with symptomatic PE and cancer have better outcomes if they are acutely managed according to international guidelines, with regards to use of anticoagulants and vena cava filters. Outcomes will consist of all-cause mortality, PE-related mortality, recurrent venous thromboembolism (VTE), and major bleeding events during the first month of follow-up after PE diagnosis.

This study will provide useful information about adherence to guidelines in cancer patients with acute PE and its association with recurrent VTE, bleeding, or death.

Notes

[illegible]

Round Table 4

Complications of therapy

Management of bleeding during therapy

Dr. Farès Moustafa

Department of Emergency

Clermont-Ferrand University Hospital

Clermont-Ferrand. France

Background

The ideal management of major bleeding in patients receiving vitamin K antagonists (VKA) for venous thromboembolism (VTE) is still not known.

Methods

We used the **RIETE** (Registro Informatizado de pacientes con Enfermedad TromboEmbólica), registry to assess the management and clinical outcomes after major bleeding in patients receiving VKA for acute VTE.

Results

From January 2013 to September 2017, 17,534 VTE patients receiving long-term VKA were recruited. Of these, 254 (1.4%) had major bleeding (gastrointestinal 75, intracranial 68, hematoma 49, genitourinary 19, other 43).

The use of pro-haemostatic agents, fresh frozen plasma, vitamin K, blood transfusion and inferior vena cava filter will be presented. During the first 48 hours, 44 patients (17%) died: 41 (93%) died of bleeding. Beyond the second day, there were no fatal bleeds, 3 patients had non-fatal major re-bleeding, 10 had recurrent VTE, two myocardial infarctions and two had an ischemic stroke.

On multivariable analysis, we identified some independent predictors for early mortality and for thromboembolic recurrences too.

Conclusions

Major bleeding in patients receiving VKA for VTE has a high mortality rate. The therapeutic approach is very heterogeneous, thus suggesting that more information is urgently needed.

Notes

[illegible]

Round Table 4

Complications of therapy

Predictors of outcome during therapy

Dr. Alfonso Tafur

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Background

The risk of mortality and the risk of thrombosis recurrence among non-selected patients with venous thromboembolism (VTE) are low. Patients with Cancer-Associated Thrombosis (CAT) bear an exponentially higher likelihood of re-thrombosis, bleeding and death.

Methods

Using the RIETE database, we studied the performance of 2 cancer specific scores in mortality and recurrence prediction.

Anchored on those results, we used recursive partitioning analysis to derive a set of predictors of 30-day mortality in CAT. The risk groups were subsequently tested in a validation cohort.

Results

In 7,948 RIETE patients with CAT, the Khorana risk score was associated with bleeding and mortality rates during treatment (Low 25.3 (95 %CI: 22.8–28.0), Intermediate 58.5 (55.5–61.7), and High KRS 120 (110–131) deaths per 100 patient-years). Similarly, the modified Ottawa score was evaluated in 11,123 CAT patients and there was a progression of the rate of recurrence during therapy (Low 6.9% (5.1–8.8), Intermediate 11.8% (10.1–13.6), and High Ottawa 21.3% (18.8–24.1) patient-year). In both studies, the scores had poor predictive performance (Khorana in mortality AUC 0.54 (95 %CI: 0.52–0.56); Ottawa in VTE recurrence 0.58 (0.6–0.6)).

In a 6,660-patient derivation cohort randomly selected from 10,025 CAT RIETE participants we detected and then validated 4 variables to discriminate 30-day mortality. White count, metastasis, mobility and pulmonary embolism defined 30-day mortality risk in CAT. The death rate was highest for those with elevated white count (25%, OR 4.6–13.4).

Conclusions

We have validated in a **RIETE** cohort a set of risk factors predictive of CAT related early mortality. Elevated white count was a stronger predictor of death than the permutation of mobility, metastasis, and pulmonary embolism.

What to do next?

External validation of our mortality prediction tool for patients with CAT.
Randomized registry opportunity to implement a therapeutic intervention stratified by death likelihood.

Notes

[illegible]

Round Table 4

Complications of therapy

Vena cava filters

Dr. Meritxell Mellado

Department of Angiology and Vascular Surgery

Hospital del Mar

Barcelona. Spain

Background

The impact of inferior vena caval filters (IVC) on outcomes of patients presenting with major bleeding during anticoagulation for venous thromboembolism (VTE), has not been thoroughly investigated.

Methods

We used patients from the **RIETE** registry, from January 2001 to September 2016, to compare the 30-day outcomes (VTE recurrences, major re-bleeding or death) in VTE patients with major bleeding during the first 3 months of anticoagulation, according to insertion of an IVC filter. A propensity score matched (PSM) analysis was performed to adjust for potential confounders.

Results

Patients receiving a filter restarted anticoagulation later and at lower doses than those not receiving a filter. On PSM analysis, patients receiving an IVC filter had a lower risk of all-cause death or fatal bleeding and a similar risk of any major re-bleeding or PE recurrences than those not receiving a filter.

Conclusions

In patients with VTE experiencing major bleeding during the first 3 months of therapy, use of IVC filters was associated with later restarting of anticoagulation, reduced fatal bleeding and reduced mortality.

What to do next?

Future efforts should help to identify safer strategies (including timing, drug, and dose) for re-initiation of anticoagulation in VTE patients who suffer from major bleeding.

Notes

[illegible]

Round Table 4

Complications of therapy

Outcomes in patients with- vs. without additional risk factors

Dr. Alessandra Bura-Rivière

Department of Vascular Medicine

Hôpital de Rangueil

Toulouse. France

Background

Recent data from the **RIETE** registry (Kamphuisen et al) suggest that after 6 months of anticoagulation, patients with cancer-associated thrombosis (CAT) may benefit of a prolonged anticoagulation beyond the sixth month. On the other hand, this attitude is associated with an increased bleeding risk.

In patients without cancer, the optimal duration on anticoagulation is determined by the presence or absence of transient associated risk factors (ARF), as immobilization or surgery. In non-cancer patients with ARF, anticoagulation can be safely stopped after 3 months, with a very low risk of recurrences.

The aim of this study was to evaluate the impact of prolonging anticoagulation beyond the sixth month on the outcomes of patients with CAT separately in patients with- and in patients without ARF (immobilization or surgery)

Methods

We compared the rates of recurrent VTE, major bleeding and death beyond six months in patients with CAT in the presence or absence of ARF (immobilization or surgery). In the two groups, we compared the outcome of patients treated for 180±30 days and those treated >210 days (prolonged treatment). We included 4,075 patients of which 632 had additional risk factors.

Results

The results will be presented during the meeting

What to do next?

We need to keep on working to identify the ideal duration of therapy for the different subgroups of cancer patients with VTE.

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Round Table 5

Miscellanea

Beating the odds in pulmonary embolism management

Dr. Deisy Barrios

Department of Pneumology

University Hospital Ramón y Cajal

Madrid. Spain

Although patients with cancer-associated thrombosis have a higher risk of recurrence, bleeding and mortality as compared with non-cancer patients, the specific characteristics of cancer patients, as comorbidities, the use of anti-tumoral therapies and the cancer progression, represent a major therapeutic challenge for choosing a long-term anticoagulant treatment.

The CLOT trial demonstrated superiority of low molecular weight heparin over warfarin for recurrence venous thromboembolism and established LMWH as the standard of care for cancer-associated VTE, but with a similar bleeding risk compared to warfarin. However, the CATCH study did not detect any difference.

The ACCP guidelines suggest the use of LMWH as long-term (first 3 months) anticoagulant therapy over VKA therapy (Grade 2C), dabigatran (Grade 2C), rivaroxaban (Grade 2C), apixaban (Grade 2C), or edoxaban (Grade 2C) in patients with DVT of the leg or PE and cancer ("cancer-associated thrombosis").

Nevertheless, LMWH requires daily subcutaneous injections, which may be inconvenient for some patients, especially those requiring long-term treatment, so an attractive alternative would be the use DOACs, but at present, there are no published randomized trials using DOAC exclusively for VTE associated with cancer and there are no direct comparisons between LMWH and DOACs.

Therefore, considering the lack of treatment data in patients with VTE and cancer, the published guidelines do not recommend the current use of DOACs in these patients. Several ongoing studies are assessing DOACs for cancer-associated thrombosis, as the HOKUSAI VTE-cancer that compares edoxaban with dalteparin and the CARAVAGGIO study that uses apixaban for treatment of VTE in patients with cancer.

We are expecting the results of these studies to open new alternatives for the treatment of our patients.

Notes

[illegible]

Round Table 5

Miscellanea

PERT fever

Dr. David Jiménez

*Department of Pneumology
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Madrid. Spain*

Pulmonary Embolism response teams (PERTs) provide rapid multidisciplinary assessment and treatment of patients with acute symptomatic pulmonary embolism (PE). However, experience and preliminary outcomes data from such teams are sparse.

Patients with cancer are at significantly higher risk of developing, and dying from acute PE. Treatment decisions for these patients require careful consideration of the interplay between the patients' cancer with their underlying comorbidities. Although the PERT model was developed to improve the quality and efficiency of care for patients with intermediate- and high-risk PE, activation of PERT for cancer patients might allow for rapid, multidisciplinary discussion among dedicated specialists.

Future studies should assess if the PERT model may represent a new standard of care for patients with cancer and acute PE.



Notes

[illegible]

Round Table 5

Miscellanea

Most common DVT sites in patients with cancer

Dr. Emmanouil Papadakis

Department of Haematology and Hemostasis

Hospital Papageorgiou

Saloniki, Greece

Background

Venous thromboembolism (VTE) is common in patients with malignancies, affecting up to 10% of this patient population. About 25% of patients incorporated in the RIETE database are cancer patients. Cancer patients are at particular high risk of major complications and VTE-related death. Most patients with cancer-related thrombosis present with DVT affecting the lower limb. Upper extremity DVT although a rare condition in the non-cancer patients it is encountered in increasing numbers in the cancer-VTE setting. Studies denote that active cancer is associated with VTE location. Location of VTE may be useful in decision making regarding cancer screening. On the other hand, VTE location, as studies demonstrate, could be related to survival of patients with cancer-associated thrombosis.

Methods

Our current study analyzes clinical presentation, characteristics, and incidence of VTE, focusing on VTE location. We compare VTE topography between cancer and non-cancer population in the **RIETE** database. Correlation between VTE location, VTE provoking factors and cancer were assessed. We further analyzed the likelihood of cancer occurrence regarding to VTE location at the index thrombotic event.

Results

Among 32,808 patients with DVT included in this analysis, 7,604 presented active cancer. Active cancer patients, compared to non-cancer DVT patients, had more often thrombosis located in the upper limbs (13.5% vs 5.7% $p<0.0001$) in rare sites (1% vs 0.1% $p<0.0001$) and multiple site DVT (2.4% vs 1.4%, $p<0.0001$). Conversely, non-cancer patients presented more often lower limb DVT (92% vs 82.4% $p<0.0001$).

Conclusions

Thrombus topography differs between cancer and non-cancer DVT patients, with upper limbs, multiple site and rare site thrombosis being more common in the cancer setting.

What to do next?

Correlate VTE location with treatment modalities, survival, and treatment complications in patients with cancer in the RIETE database.

Notes

[illegible]

Round Table 5

Miscellanea

Interventional therapies for PE

Dr. Miguel Ángel de Gregorio

Department of General Surgery

University Clinic Hospital Lozano Blesa

Zaragoza. Spain

Interventional Radiology (IR) procedures like Pulmonary Arteriography and Phlebography have played an important role in the diagnosis of pulmonary embolism (PE) and peripheral venous thrombosis in the past decades. Today, Ultrasound and Computed Tomography are the gold standard techniques for non-invasive diagnosis, keeping IR for therapeutic procedures when needed.

Inferior Vena Cava Filters (IVCF) are a therapeutic and prophylactic method that, under the adequate indication, avoid thrombus migration from the extremities to pulmonary arteries. Between January and March, 2016 we implanted 246 IVCFs. Retrieval could be achieved in the 83.7% of the patients. Ten IVCFs were impossible to retrieve. No repeated PE was identified in any of these patients. Ten patients died in the first month period after their implantation.

When massive PE occurs, it requires systemic or in situ fibrinolytic treatment. In a period of eight years (January 2001-December 2009) we treated 111 patients suffering of massive PE via local fibrinolysis by urokinase and mechanical fragmentation with pigtail catheter. We obtained a technical success of 100%. The Miller Index improved from 0.7 ± 0.12 pre-treatment to 0.09 ± 0.16 post-treatment. The mean pulmonary arterial pressure (mPAP) dropped from 39.93 ± 7.0 mmHg to 20.47 ± 3.3 mmHg at the 30-90 days re-evaluation. Seven patients died after 30 days of the PE event (three due to right ventricle failure, three of neoplastic disease and one from intracranial hemorrhage).

Our group is currently treating massive PE with another catheter directed technique: thrombo-aspiration combined with low doses of urokinase, with satisfactory and promising results decreasing the time and total dosage of fibrinolysis and mPAP more rapidly.

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Round Table 6 Concomitant conditions

Thrombophilia

Dr. Juan José López

Department of Internal Medicine

University Hospital Germans Trias i Pujol

Badalona, Barcelona. Spain

Background

The role of certain forms of thrombophilia (factor V Leiden [FVL] and prothrombin G20210A [PTM] mutations) in cancer patients with venous thromboembolism (VTE) has not been consistently investigated.

Methods

We used the **RIETE** database to compare the rate of VTE recurrences and bleeding events occurring during the course of anticoagulation in patients with active cancer, comparing FVL carriers, PTM carriers and non-carriers.

Results

From March 2001 to September 2017, 1264 cancer patients underwent thrombophilia testing. Of these, 124 (9.8%) were FVL carriers, 111 (8.8%) PTM carriers and 1029 (81%) non-carriers. During the course of anticoagulant therapy, 46 patients developed DVT recurrences, 30 had PE recurrences (6 died), 42 had major bleeding (4 died) and 55 had non-major bleeding. The results will be presented and discussed.

Conclusions

Our findings may contribute to decision-making regarding the duration of anticoagulant therapy in selected cancer patients with VTE and FVL or PTM mutation.

What to do next?

We need to include more patients in the **RIETE** database with active cancer and thrombophilia testing, to increase our cohort and try to achieve significant differences among subgroups.

Notes

[illegible]

Round Table 6

Concomitant conditions

Renal insufficiency

Dr. Laurent Bertoletti

Department of Vascular Medicine and Therapeutics

Hôpital Nord, CHU

Saint-Étienne. France

Background

Acute pulmonary embolism (PE) may induce acute kidney injury (AKI). The frequency and impact of AKI on the prognosis of patients with acute PE have not been consistently studied.

Methods

Using data from the Registro Informatizado de pacientes con Enfermedad TromboEmbólica (**RIETE**) registry, we assessed the frequency of AKI at baseline and its influence on the 30-day mortality in patients with symptomatic, acute PE. AKI was considered according to the “Kidney Disease: Improving Global Outcomes” definition. We used multivariate analysis to assess the influence of AKI on 30-day mortality.

Results

The study included 21,131 patients with acute PE, of whom 6,222 (29.5%) had AKI at baseline. Of these, 4385 patients (21%) were in stage 1, 1385 (6.5%) in stage 2 and 452 (2%) in stage 3. The proportion of patients with systolic blood pressure (SBP) levels <90 mm Hg in those with no AKI, AKI stage 1, AKI stage 2 and AKI stage 3 was: 2.8%, 5.3%, 8.8% and 12%, respectively ($p < 0.001$). After 30 days, 1236 patients (5.85%) had died. Overall mortality was 4% in patients with no AKI, 8.4% in AKI stage 1, 14% in AKI stage 2, 17% in AKI stage 3, all $p < 0.001$. On multivariable analysis, AKI was independently associated with an increased risk of death at 30 days (odds ratio=1.25; 95%CI: 1.02-1.54), after adjusting for SBP levels <90 mm Hg, age >65 years, chronic heart failure or lung disease, cancer, anemia and liver cirrhosis.

Conclusions

One in every 3-4 patients with acute PE had AKI. AKI at baseline was an independent predictor of mortality at 30 days. This study suggests that PE could be considered a risk factor for AKI and AKI should to be considered as a prognostic factor in acute PE.

Notes

[illegible]

Round Table 6 Concomitant conditions

Radiation therapy

Dr. Jean-Baptiste Guy

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Institut de cancérologie de la Loire – Lucien Neuwirth

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Background

Cancer patients are at high risk of venous thromboembolism, particularly during cancer treatment. Conversely to chemotherapy, data on the epidemiology and clinical features of venous thromboembolism during radiation therapy are scarce. There is lack of evidence on the influence of radiation therapy (RT) on outcome in cancer patients with acute venous thromboembolism (VTE).

Methods

We used the **RIETE** (Registro Informatizado de pacientes con Enfermedad TromboEmbólica) database to assess the clinical characteristics and outcome of prospectively collected consecutive patients with cancer-associated thrombosis occurred during the course of radiation therapy for cancer. Death, venous thromboembolism recurrences and major bleeding rates during long-term follow-up according to cancer site and treatment were compared.

Results

9284 patients with active cancer and VTE were enrolled in **RIETE**: 4605 with pulmonary embolism (PE) and 4679 with deep vein thrombosis (DVT). In all, 1202 (13%) were receiving RT. This last sub-population had a higher rate of PE recurrences and a similar rate of DVT recurrences or major bleeding than those not receiving RT. Patients on RT had a higher rate of cerebral bleeding.

Conclusions

In this cohort of cancer patients with VTE, a significant proportion of them received RT before VTE; the latter experienced a higher risk of cerebral bleeding.

What to do next?

Radiation dose and technique, target volumes, fractionation scheme should be evaluated and above all selected populations and localizations, in order to assess a preventive attitude. The risk of VTE in cancer patients is indeed multifactorial and the potential role of RT as a VTE risk factor requires further research (RIT cohort, available on [clinicaltrials.gov: NCT02696447](https://clinicaltrials.gov/ct2/show/study/NCT02696447)).

Notes

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Round Table 6

Concomitant conditions

Arterial ischemic events

Dr. Benjamin Brenner

*Department of Haematology
Rambam Health Care Campus
Haifa, Israel*

Background

Venous thromboembolism (VTE) is common in patients with malignancies, affecting up to 10% of this patient population. About 25% of patients incorporated in the RIETE database are cancer patients. The association between atherosclerotic cardiovascular disease (CVD) and VTE has been established. However, the epidemiology of arterial ischemic events in cancer patients has not been fully determined.

Methods

The current study analyzed clinical characteristics, risk factors and incidence of VTE, arterial ischemic events and major bleeding in patients with active cancer in the **RIETE** database. Correlation between these events and cancer type, status (metastatic) and therapy was assessed. We further analyzed the impact of antithrombotic treatment strategies on the development of these events.

Results

Among 4,809 patients with active cancer revealed in this analysis, 499 VTE recurrences, 346 major bleeding events and 63 arterial events were identified. All types of events were more common (65%) among patients with metastatic disease. Cardiovascular risk factors were more frequent in patients who developed arterial events. The time lapse from VTE diagnosis to an arterial event was comparable to that observed in major bleeding events and considerably shorter than in VTE recurrence (median of 36, 35 and 97 days, respectively). Bleeding was the leading fatal event in the study population, while the cumulative mortality rate at one year due to arterial ischemic events was similar to that related to pulmonary embolism recurrence. Antiplatelet agents were used in only 6% of patients who developed arterial events.

Conclusions

Arterial ischemic events and major bleeding appear early in the course of VTE patients with active cancer and are an important cause of their death. Antiplatelet agents are hardly used in this clinical setting.

What to do next?

Compare arterial ischemic events in patients with and without cancer in the RIETE database. Identify patient categories at high risk of arterial ischemic events that may benefit from improved antithrombotic strategies.



Notes

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Round Table 6

Concomitant conditions

Drug-drug interactions. Chemotherapy and anticoagulation

Dr. David Conde

*Department of Pharmacy
Hospital del Mar
Barcelona. Spain*

Background

Onco-hematological patients are particularly susceptible to drug-drug interactions (DDIs) as often on multiple combined treatments. A DDI is an increase or decrease in the clinical effect of a drug due to interference by another drug, potentially compromising treatment outcomes and, occasionally, leading to adverse events. DDIs are classified into pharmacodynamics (PD) and pharmacokinetics (PK). PK-DDI may affect the absorption, distribution, metabolism, or elimination of drugs. The most significant PK-DDIs are those affecting the metabolism of hepatic microsomal enzymes (CYP450). PD-DDI occur when an additive, synergistic or antagonistic effect occurs when two drugs are used concomitantly. Remarkably, cancer patients are not routinely checked for DDIs worldwide.

Methods

Studies regarding DDIs in clinical practice are heterogeneous due to lack of drug information, important discrepancies between different databases and study design. Besides, there are studies determining adverse drug events (ADE) frequency related to DDIs.

Results

Despite advances in DDI identification technology and accessibility to patient-centered educational materials, the prevalence rate of patients with ADE related to DDI is over 30%. ADE are commonly equated with drug overexposure; however, reduction of drug efficacy is equally detrimental.

Conclusions

It is mandatory to know medications coadministered with oncology drugs to recognize DDIs. Specialty pharmacists conduct comprehensive DDI assessments.

The new era in personalized cancer treatment with a great number of new drugs, requires prescribers to be more knowledgeable about PK/PD. Most new drugs are associated with multiple, clinically significant DDIs. Risk is increased by comedications for other chronic diseases.

What to do next?

Health care systems should be encouraged to apply the same level of detailed institutional policies currently applied to weight-based anticancer drug calculations to the amelioration and prevention of DDIs that may result in dramatic effects on drug exposure. Ideally, this would include automated checking of potential DDIs (electronic medical record) and/or careful medication review by an experienced pharmacist.

Notes

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Conference

Oncologic surgery and VTE

Dr. Juan Ignacio Arcelus

Department of General Surgery

University Hospital Virgen de las Nieves

Granada. Spain

Background

Venous thromboembolism (VTE) represents a serious complication in oncologic surgery. Recent studies have shown that the risk of VTE persists several weeks after this type of surgery. This presentation will address the form and natural history of VTE after cancer surgery.

Methods

We will review the literature and present the results of a recently published study that analyzes the data from **RIETE**, focusing on the form of presentation as DVT or PE, the moment of VTE detection, and main outcomes in patients who developed VTE after an operation for abdominal and pelvic cancer surgery. Variables related to the form and moment of presentation, as well as complications during treatment will be analyzed.

Results

Of the 766 patients with postoperative symptomatic VTE included in the analysis, 52% presented as pulmonary embolism (PE). Most patients (80%) had VTE detected past the first postoperative week, and 38% after one month. Overall, 54% of patients with VTE suffered this complication after hospital discharge. The average number of days between surgery and VTE were 26; however, the duration of prophylaxis –received by 75% of patients– was only 13 days. On a multivariate analysis, colorectal and genitourinary cancers, the use of radiotherapy, and increased levels of hemoglobin were associated with VTE after hospital discharge. Adverse outcomes (bleeding, death, thrombosis recurrences) occurred in 34% of patients who developed VTE before discharge compared with 24% in those with VTE thereafter.

Conclusions

Our results, as well as the available evidence, indicate that postoperative VTE occurs after hospital discharge in many patients operated for cancer, particularly in those operated for colorectal, urologic, and gynecological tumors. Recent guidelines provide non-coincident recommendations regarding the extension of prophylaxis in this population. As a result, the use of prophylaxis in real clinical practice remains suboptimal.

What to do next?

We need more studies trying to better identify patients who would benefit from extended prophylaxis after oncologic surgery.

Notes

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