PREVENTION AND TREATMENT OF CINV & VTE IN ONCOLOGY PATIENTS
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Providence Alaska Medical Center

Objectives
- Discuss the pathophysiology of chemotherapy-induced nausea vomiting (CINV) and venous thromboembolism (VTE) in cancer patients
- Summarize published guidelines for prevention and treatment of CINV and evaluate recently approved therapeutic options
- Explain the use of target specific oral anticoagulants (TSOACs) for prophylaxis and treatment of VTE in oncology patients

Case 1
- ML is a 78 yo male diagnosed with small cell lung cancer. He will be receiving the following regimen:
  - cisplatin 25 mg/m2 days 1, 2, 3
  - etoposide 100 mg/m2 days 1, 2, 3
- PMH: chronic alcohol consumption, 150 pack year history of smoking, hypertension, skin cancer

Which of the following meets standard of care according to the MASCC/ESMO, ASCO, and NCCN guidelines to prevent CINV in ML?
A. NK-1 RA + DEX + 5-HT3 RA
B. NK-1 RA + 5-HT3 RA
C. DEX + 5-HT3 RA
D. NK-1 RA + DEX

Case 2
- DK is a 48 yo female with Stage III HER2-positive breast cancer and incomplete control of CINV
- Starting adjuvant therapy with docetaxel, carboplatin, and trastuzumab after lumpectomy and sentinel node biopsy
- No significant medical history, lifelong non-smoker, does not drink alcohol
- Cycle 1: Prophylaxis for CINV with ondansetron and dexamethasone before chemotherapy, but the evening after chemotherapy, she has nausea and vomiting
- Prochlorperazine relieves emesis, but nausea continues for 3 days post-chemotherapy

Which of the following would not be an appropriate intervention for prevention of CINV with DK’s next cycle of chemotherapy?
A. Add NK-1 RA to DEX and 5-HT3 RA
B. Add lorazepam to be taken prior to arrival for chemo
C. Add metoclopramide
D. Add scopolamine patch
E. Add promethazine

Chemotherapy Induced Nausea Vomiting
**CINV Definitions**

- **Acute onset**: Occurs within a few minutes to several hours, resolves within 24 hours.
- **Delayed onset**: Occurs > 24 hours after chemo.
- **Anticipatory**: Occurs prior to next chemo.
- **Breakthrough**: Vomiting despite prophylactic treatment.
- **Refractory**: Antiemetic prophylaxis and/or rescue have failed in earlier cycles.

**Mechanisms**

- **Principle neuroreceptors**: serotonin (5-HT3) receptors, dopamine receptors.
- **Other neuroreceptors**: acetylcholine, corticosteroid, histamine, cannabinoid, opiate, neurokinine-1 (NK-1).

**Risk Factors**

- **Chemotherapeutic agent**
- **Dosage of chemotherapy**
- **Schedule and route of administration**
- **Radiation therapy**
- **Individual patient variability**
  - Age
  - Sex
  - Prior chemo
  - History of alcohol use
  - History of morning/motion sickness

**Chemotherapy Emetogenicity**

<table>
<thead>
<tr>
<th>High risk (&gt;90% frequency)</th>
<th>Moderate risk (30-90% frequency)</th>
<th>Low risk (10-30% frequency)</th>
<th>Minimal risk (&lt;10% frequency)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AC combination</strong></td>
<td><em>Cisplatin</em> &gt;250 mg/m²</td>
<td><em>Doxorubicin</em> &gt;60 mg/m²</td>
<td><em>Doxorubicin</em> &gt;250 mg/m²</td>
</tr>
<tr>
<td><em>Carboplatin</em> &gt;250 mg/m²</td>
<td><em>Cisplatin</em> &gt;1500 mg/m²</td>
<td><em>Etoposide</em> &gt;90 mg/m²</td>
<td><em>Mitoxantrone</em> ≤300 mg/m²</td>
</tr>
<tr>
<td><em>Cytarabine</em> &gt;250 mg/m²</td>
<td><em>Pazopanib</em> &gt;1200 mg/m²</td>
<td><em>Vincristine</em> &gt;200 mg/m²</td>
<td><em>Fludarabine</em> &gt;1000 mg/m²</td>
</tr>
<tr>
<td><em>Doxorubicin</em></td>
<td><em>Carboplatin</em> &gt;200 mg/m²</td>
<td><em>Danocrine</em> &gt;100 mg/m²</td>
<td><em>Fludarabine</em> &gt;1000 mg/m²</td>
</tr>
<tr>
<td><em>Etoposide</em> &gt;90 mg/m²</td>
<td><em>Cytarabine</em> &gt;200 mg/m²</td>
<td><em>Cyclophosphamide</em> &gt;250 mg/m²</td>
<td><em>Etoposide</em> ≤50 mg/m²</td>
</tr>
<tr>
<td><em>Ifosfamide</em></td>
<td><em>Cisplatin</em> &gt;250 mg/m²</td>
<td><em>Etoposide</em> &gt;90 mg/m²</td>
<td><em>Etoposide</em> ≤50 mg/m²</td>
</tr>
<tr>
<td><em>Ifosfamide</em> &gt;12-15 million IU/m²</td>
<td><em>Cyclophosphamide</em> &gt;60 mg/m²</td>
<td><em>Etoposide</em> &gt;90 mg/m²</td>
<td><em>Etoposide</em> ≤50 mg/m²</td>
</tr>
<tr>
<td><em>Mitoxantrone</em> &gt;60 mg/m²</td>
<td><em>Gastroparesis</em> &gt;60 mg/m²</td>
<td><em>Vincristine</em> &gt;250 mg/m²</td>
<td><em>Ifosfamide</em> ≤50 mg/m²</td>
</tr>
<tr>
<td><em>Valrubicin</em></td>
<td><em>Cisplatin</em> ≤300 mg/m²</td>
<td><em>Vincristine</em> &gt;250 mg/m²</td>
<td><em>Ifosfamide</em> ≤50 mg/m²</td>
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<tr>
<td><em>Vincristine</em> &gt;250 mg/m²</td>
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<td><em>Vincristine</em> &gt;250 mg/m²</td>
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<td><em>Ifosfamide</em> ≤50 mg/m²</td>
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**Chemotherapy Emetogenicity**

- **High risk (90%)**: Acute onset, delayed onset, anticipatory.
- **Moderate risk (30-90%)**: Delayed onset, breakthrough, refractory.
- **Low risk (10-30%)**: Individual patient variability.
- **Minimal risk (<10%)**: Chemotherapeutic agent, dosage, schedule, radiation therapy.

**Risk Factors**

- **Chemotherapeutic agent**
- **Dosage of chemotherapy**
- **Schedule and route of administration**
- **Radiation therapy**
- **Individual patient variability**
  - Age
  - Sex
  - Prior chemo
  - History of alcohol use
  - History of morning/motion sickness
**Antiemetic Medications**

<table>
<thead>
<tr>
<th>Serotonin (5-HT3) antagonists</th>
<th>NK1 Antagonists</th>
<th>Phenothiazine</th>
<th>Antihistamines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dolasetron</td>
<td>Aprepitant</td>
<td>Prochlorperazine</td>
<td>Diphenhydramine</td>
</tr>
<tr>
<td>Granisetron</td>
<td>Fosaprepitant</td>
<td>Promethazine</td>
<td>Hydroxyzine</td>
</tr>
<tr>
<td>Ondansetron</td>
<td>Palonosetron</td>
<td>Perphenazine</td>
<td></td>
</tr>
<tr>
<td>Palonosetron</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All are effective in acute nausea and/or vomiting</td>
<td></td>
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</tr>
</tbody>
</table>

**Serotonin (5-HT3) Receptor Antagonists**

- **Palonosetron**
  - 100-fold higher binding affinity
  - Half-life ~40 hours
- **Ondansetron**
  - Max dose IV - 16 mg
- **Granisetron**
  - Transdermal system for CINV
  - Apply 24-48 hours prior to first dose of chemo
  - Max duration – 7 days

**NK-1 Receptor Antagonist**

- Increased infection rate
  - 6% vs 2% (P<0.001)
- Most common adverse event seen clinically - hiccups

**Formulations**

- **Aprepitant** (PO) – days 1, 2, 3
- **Fosaprepitant** (IV) – day 1

**Metabolism**

- CYP3A4 – substrate, inhibitor
- CYP2C9 – inducer

**Olanzapine**

- **Olanzapine vs Aprepitant**
  - Acute: 97% vs 87%
  - Delayed: 77% vs 73%
- Caution in elderly?

**Guideline Summary: Acute CINV**

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>5-HT, RA + dexamethasone + NK antagonist</td>
<td>Dexamethasone days 3-5 or 3-6</td>
<td>Dexamethasone and aprepitant†</td>
</tr>
<tr>
<td>Moderate</td>
<td>5-HT, RA + dexamethasone</td>
<td>5-HT, RA or dexamethasone days 2-3</td>
<td>Dexamethasone</td>
</tr>
<tr>
<td>Low</td>
<td>Dexamethasone</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

1. palonosetron preferred

**Guideline Summary: Delayed CINV**

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Dexamethasone days 2-3</td>
<td>Dexamethasone days 2-4</td>
<td>Dexamethasone and aprepitant†</td>
</tr>
<tr>
<td>Moderate</td>
<td>Dexamethasone days 2-3</td>
<td>5-HT, RA or dexamethasone days 2-3</td>
<td>Dexamethasone</td>
</tr>
<tr>
<td>Low</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

*If using olanzapine-based regimen
† dexamethasone only if fosaprepitant used on day 1
CINV

- Pharmacotherapeutic principles
  - Goal is prevention of nausea/vomiting
  - Evaluate a patient for risk factors
  - Choose multiple drugs from different classes

Akynzeo® (netupitant/palonosetron)

WHAT?
- Fixed dose combination: netupitant 300 mg/palonosetron 0.5 mg orally x 1 dose
  - NK-1 RA + 5-HT3 RA

- Synergism \(\rightarrow\) inhibition of substance P response

WHY?
- Combination antiemetic regimens targeting multiple molecular pathways are standard of care
  - Moderate emetogenic: Dexamethasone + 5-HT3 RA
  - Highly emetogenic: 5-HT3 RA + NK-1 RA + Dex
- Adherence to guidelines is suboptimal

Phase III, multicenter, randomized, double-blind, double-dummy, parallel group
- Spanned 117 sites in 15 countries

Study designed to demonstrate NEPA superiority over PALO (palonosetron) based on proportion of patients with CR during delayed phase

Primary efficacy endpoints
- CR during delayed phase
  \(\Rightarrow\) no emesis, no rescue medication

Secondary efficacy endpoints
- CR during acute phase (0-24 hrs)
- CR overall (0-120 hrs)
- Complete Protection (CR + no significant nausea)
- No emesis and no significant nausea (VAS <25 mm) during acute, delayed and overall phase

Use of rescue medication \(\Rightarrow\) treatment failure
Akynzeo® (netupitant/palonosetron)

**Methods**
- Diary
  - Vomiting
  - Nausea
  - Visual analog scale
- Functional Living Index Emesis (FLIE)
  - Proportion of patients with scores reflecting no impact on daily life (NIDL)

**Safety**
- Adverse events
- Clinical laboratory evaluations
- Physical examinations
- Vital signs
- Electrocardiogram

**Statistics**
- Sample size needed for superiority: 661 per group
  - 90% power to detect 9% difference
- Efficacy analysis
  - All pts randomized and received protocol-required MEC and study treatment
- Safety analysis
  - All pts who received study treatment and had at least one safety assessment

**Primary efficacy endpoint**
- NEPA CR 76.9% vs PALO 69.5% (P=0.001)

**Secondary efficacy endpoints:**

<table>
<thead>
<tr>
<th></th>
<th>NEPA (N=724)</th>
<th>PALO (N=725)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No emesis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Acute</td>
<td>90.9%</td>
<td>87.3%</td>
<td>0.025</td>
</tr>
<tr>
<td>- Delayed</td>
<td>81.8%</td>
<td>78.6%</td>
<td>0.004</td>
</tr>
<tr>
<td>- Overall</td>
<td>78.8%</td>
<td>72.1%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>No significant nausea</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Acute</td>
<td>87.3%</td>
<td>87.9%</td>
<td>0.740</td>
</tr>
<tr>
<td>- Delayed</td>
<td>76.9%</td>
<td>71.3%</td>
<td>0.014</td>
</tr>
<tr>
<td>- Overall</td>
<td>74.6%</td>
<td>69.1%</td>
<td>0.020</td>
</tr>
<tr>
<td>Complete protection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Acute</td>
<td>82.3%</td>
<td>81.1%</td>
<td>0.528</td>
</tr>
<tr>
<td>- Delayed</td>
<td>67.3%</td>
<td>60.3%</td>
<td>0.005</td>
</tr>
<tr>
<td>- Overall</td>
<td>63.8%</td>
<td>57.9%</td>
<td>0.020</td>
</tr>
</tbody>
</table>

**Limitations**
- Depended on patients reporting data in diary
- Fair comparison?
  - NEPA + DEX = 5-HT3 RA + NK-1 RA + DEX
  - PALO + DEX = 5-HT3 RA + DEX

**Strengths**
- May improve adherence to guidelines
- Oral formulation

**Cost**
- Fosaprepitant + Palonosetron ≈ Netupitant/ Palonosetron
- Fosaprepitant + Ondansetron ≤ Netupitant/ Palonosetron
Akynzeo® (netupitant/palonosetron)

- **Safety**
  - NEPA severe adverse event (0.7%)
    - Headache
    - Constipation

- **Phase III, multicenter, randomized, double-blind, double-dummy, parallel group**
  - Spanned 59 sites in 10 countries

- **Goal:** Characterize safety profile of netupitant/palonosetron over a duration of at least six cycles

Akynzeo® (netupitant/palonosetron)

- **Results**
  - NEPA - numerical advantage
  - CR rates similar
  - Proportions of patients without nausea
    - NEPA - 84-92%
    - APR + PALO - 81-87%

Akynzeo® (netupitant/palonosetron)

- **Limitations**
  - May have not been powered to show a difference between the two groups

- **Strengths**
  - Showed safety and efficacy when using NEPA throughout multiple chemotherapy cycles

Akynzeo® (netupitant/palonosetron)

- **Key points**
  - Another option for CINV that is all oral
  - Check for duplication of therapy
  - Possible benefit of simplifying CINV regimen
Case 1

ML is a 78 yo male diagnosed with small cell lung cancer. He will be receiving the following regimen: cisplatin 25 mg/m² days 1, 2, 3 etoposide 100 mg/m² days 1, 2, 3

PMH: chronic alcohol consumption, 150 pack year history of smoking, hypertension, skin cancer

Which of the following meets standard of care according to the MASCC/ESMO, ASCO, and NCCN guidelines to prevent CINV in ML?

A. NK-1 RA + DEX + 5-HT³ RA
B. NK-1 RA + 5-HT³ RA
C. DEX + 5-HT³ RA
D. NK-1 RA + DEX

Is Alkynzeo an appropriate agent for first line CINV prevention for ML?

A. Yes
B. No

Case 2

DK is a 48 yo female with Stage III HER2-positive breast cancer and incomplete control of CINV starting adjuvant therapy with docetaxel, carboplatin, and trastuzumab after lumpectomy and sentinel node biopsy

No significant medical history, lifelong nonsmoker, does not drink alcohol

Cycle 1: Prophylaxis for CINV with ondansetron and dexamethasone before chemotherapy, but the evening after chemotherapy, she has nausea and vomiting

Prochlorperazine relieves emesis, but nausea continues for 3 days post-chemotherapy

Which of the following would not be an appropriate intervention for prevention of CINV with DK’s next cycle of chemotherapy?

A. Add NK-1 RA to DEX and 5-HT³ RA
B. Add lorazepam to be taken prior to arrival for chemo
C. Add metoclopramide
D. Add scopolamine patch
E. Add promethazine

Conclusions

Several neurotransmitters play a role in the physiology of CINV

serotonin, dopamine, acetylcholine, corticosteroid, histamine, cannabinoid, opiate, neurokinine-1 (NK-1)

Guideline summary

MEC: 5-HT³ RA + DEX
HEC: 5-HT³ RA + NK-1 RA + DEX
NEPA may have some value in that it helps adhere to the CINV guidelines
NEPA’s role in CINV has not yet been determined

Self-Assessment Questions

ML is a 78 yo male diagnosed with small cell lung cancer. He will be receiving the following regimen: cisplatin 25 mg/m² days 1, 2, 3 etoposide 100 mg/m² days 1, 2, 3

PMH: chronic alcohol consumption, 150 pack year history of smoking, hypertension, skin cancer

After received chemotherapy he calls to the clinic and complains that his left lower leg is warm to the touch and swollen. Doppler reveals LLE DVT.

What are the patient’s risk factors for DVT?

How should his DVT be treated?
Historically

- In 1823, Jean-Baptiste Bouillaud a French physician published what was reported the first association between cancer and thrombosis
- In 1865, another French physician Armand Trousseau reported an association between gastric cancer and venous thrombosis

Pathophysiology

Venous thromboembolism (VTE) is a common complication and life-threatening in oncology patients

- Venous manifestations of cancer-associated thrombosis included deep vein thrombosis (DVT) and pulmonary embolism (PE) as well as visceral and splanchnic vein thrombosis
- Cancer and chemotherapy are both well known risk factors for development of venous thromboembolism

Prevalence

- Incidence:
  - Type and frequency of thrombosis varies, occurs in about 15% cancer patients
  - Represents 20% of all cases of VTE
  - Analysis of 932 patients receiving cisplatin-based chemo: 18.1% VTE within 4 weeks of last dose

- Etiology
  - Multifactorial, risk factors are additive
  - Rarely the first symptom of malignancy

VTE Predictive Model

<table>
<thead>
<tr>
<th>Patient Characteristic</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very High Risk: Stomach, Pancreatic Cancer</td>
<td>2</td>
</tr>
<tr>
<td>High Risk: Lung, lymphoma, gynecologic, and genitourinary (excludes prostate)</td>
<td>1</td>
</tr>
<tr>
<td>Platelet count ≥ 350,000/mm³</td>
<td>1</td>
</tr>
<tr>
<td>Leukocyte count &gt; 11,000/mm³</td>
<td>1</td>
</tr>
<tr>
<td>Hemoglobin &lt; 10 g/dl or use of Erythropoiesis stimulating agent</td>
<td>1</td>
</tr>
<tr>
<td>Body Mass Index ≥ 35</td>
<td>1</td>
</tr>
</tbody>
</table>

Sum the score
- 0 = low risk (0.3% incidence)
- 1-2 = intermediate risk (2.0% incidence)
- ≥ 3 = high risk (6.7% incidence)

Primary Prevention

<table>
<thead>
<tr>
<th>Study</th>
<th>Medication</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>FAMOUS</td>
<td>Dalteparin 5,000 units SQ daily or placebo for 9 months</td>
<td>No difference in survival or VTE (3.4% vs 2.4%)</td>
</tr>
<tr>
<td>CONKO-004</td>
<td>Enoxaparin 1 mg/kg vs observation (pancreatic CA)</td>
<td>VTE in 5% enoxaparin patients vs. 14.5% observation (p&lt;0.01)</td>
</tr>
<tr>
<td>FRAGEM</td>
<td>Full-dose dalteparin vs. observation (pancreatic CA)</td>
<td>VTE in 3.4% dalteparin vs 23% observation (p&lt;0.02)</td>
</tr>
</tbody>
</table>

Primary Prevention

No routine DVT/VTE prophylaxis in ambulatory cancer patients (ASCO, CHEST, NCCN)

- Exceptions:
  - Anti-angiogenesis agents: thalidomide, lenalidomide with chemotherapy or dexamethasone
  - Pancreatic/lung cancer patients (international guidelines) w/ low bleeding risk
  - Surgery oncology patients: continue VTE ppx up to 4 weeks post-op if high risk
    - GI malignancy surgery, VTE hx, anesthesia > 2 hours, bed rest > 4 days, advanced stage dx, age > 60 years


VTE Prophylaxis

- Recommended drug therapy
  - Enoxaparin (Lovenox) 40mg once-daily
  - Dalteparin 5000 units SQ once-daily
  - Fondaparinux (Arixtra) 2.5mg once-daily
  - Heparin (UFH) 5,000 units every 8hrs

- Subcutaneous UFH 6,000 units once 12 hours has been used, but has been shown less effective in oncologic patients
  - J Clin Oncol 2013;31(17):2189-2204

VTE Treatment

- Initial therapy
  - LMWH > UFH continuous infusion for the initial 5-10 days anticoagulation
    - Enoxaparin / Dalteparin
  - Use if platelets > 50,000 and no evidence of bleeding
  - 5 – 7 days recommended overlap with warfarin with 2 days of INR >2

- Long-term therapy
  - Dalteparin* 200units/kg daily x 1 month, then 150units/kg daily for duration of therapy
  - Enoxaparin 1.5mg/kg daily or 1mg/kg twice daily
  - Warfarin dose adjusted to maintain INR 2-3
    - CLOT trial: recurrence in 16% warfarin patients vs. 8% dalteparin patients
  - Up to 6 months depending on risk/response

Target Specific Oral Anticoagulants

- Oral anticoagulants not recommended by any guidelines for cancer patients
  - Concern over absorption, GI bleeding
  - Studies include few patients with malignancy

<table>
<thead>
<tr>
<th>Study</th>
<th>Agent</th>
<th>% of patients with malignancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>RECOVER</td>
<td>Dabigatran</td>
<td>5%</td>
</tr>
<tr>
<td>EINSTEIN</td>
<td>Rivaroxaban</td>
<td>6.8%</td>
</tr>
<tr>
<td>AMPLIFY-EXT</td>
<td>Apixaban</td>
<td>1.8% (2.5mg), 1.1% (5mg)</td>
</tr>
</tbody>
</table>


Self-Assessment Questions

ML is a 78 yo male diagnosed with small cell lung cancer. He will be receiving the following regimen:
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- etoposide 100mg/m2 days 1, 2, 3
  - PMH: chronic alcohol consumption, 150 pack year history of smoking, hypertension, skin cancer
  - After received chemotherapy he calls to the clinic and complains that his left lower leg is warm to the touch and swollen. Doppler reveals LLE DVT.
  - What are the patient’s risk factors for DVT?
  - How should his DVT be treated?
Self-Assessment Questions

- After receiving chemotherapy, he calls to the clinic and complains that his left lower leg is warm to the touch and swollen. Doppler reveals LLE DVT.
- What are the patient's risk factors for DVT?
- How should his DVT be treated?
  A. Warfarin
  B. Rivaroxaban
  C. LMWH
  D. Eliquis

Conclusions

- Anticoagulants are not currently recommended to improve survival in patients with cancer without VTE per NCCN and ASCO guidelines
- FAMOUS study found no survival benefit in advanced stage patients at 12 months (with no preexisting DVT/PE)
- TSOACs are currently not recommended due to lack of published trials showing efficacy

Objectives

- Discuss the pathophysiology of chemotherapy-induced nausea vomiting (CINV) and venous thromboembolism (VTE) in cancer patients
- Summarize published guidelines for prevention and treatment of CINV and evaluate recently approved therapeutic options
- Explain the use of target specific oral anticoagulants (TSOACs) for prophylaxis and treatment of VTE in oncology patients

Questions

- Discuss the pathophysiology of chemotherapy-induced nausea vomiting (CINV) and venous thromboembolism (VTE) in cancer patients
- Summarize published guidelines for prevention and treatment of CINV and evaluate recently approved therapeutic options
- Explain the use of target specific oral anticoagulants (TSOACs) for prophylaxis and treatment of VTE in oncology patients