Retrospective Study to Evaluate Nausea, Vomiting, and Hypersensitivity Reactions in Patients Receiving FOLFOX for Colorectal Cancer at an Infusion Center Not Routinely Administering Prophylactic Dexamethasone

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BACKGROUND

- FOLFOX is a first-line treatment for metastatic colorectal cancer[1]
  - Oxaliplatin 85 mg/m^2 IV over 2 hours on day 1
  - Leucovorin 400 mg/m^2 IV over 2 hours on day 1
  - 5-Fluorouracil 400 mg/m^2 IV bolus on day 1
  - 5-Fluorouracil 1200 mg/m^2/day IV continuous infusion on days 2 and 3
- Following surgery, patients should receive FOLFOX every 2 weeks for a total of 12 cycles[1]
- FOLFOX is categorized as a moderately emetogenic chemotherapy regimen[2]
  - National Comprehensive Cancer Network (NCCN) recommends two prophylactic antiemetics–a serotonin (5-HT3) antagonist and a steroid–for patients receiving FOLFOX[2]
  - Lehigh Valley Health Network (LVHN) routinely administers only a 5-HT3 antagonist due to a perceived increase in hyperglycemia associated with steroid use
- Oxaliplatin is associated with an increased risk of hypersensitivity reactions[3]
  - A histamine-2 (H2) antagonist, a histamine-1 (H1) antagonist, and a steroid may be used as premedications to decrease the risk of FOLFOX hypersensitivity reactions[4]
  - LVHN does not routinely premedicate for hypersensitivity reactions
- Patients may receive reduced or delayed doses of FOLFOX due to the nausea, vomiting, and hypersensitivity reactions associated with FOLFOX
  - Dose intensity is related to the overall survival of patients with breast cancer who receive CMF[5]
  - Dose intensity is related to the overall survival of patients with diffuse large B-cell lymphoma who receive CHOP[6]
  - Dose intensity may be related to the overall survival of patients with colorectal cancer who receive FOLFOX
- The purpose of this study is to assess the importance of dexamethasone as a routine premedication for FOLFOX

PRIMARY OBJECTIVE

- To determine the rate of nausea, vomiting, and hypersensitivity reactions in patients receiving FOLFOX at an infusion center not routinely administering prophylactic dexamethasone

SECONDARY OBJECTIVES

- To determine the percentage of patients who complete 12 cycles of full dose FOLFOX
- To determine the average relative dose intensity (RDI) for patients receiving FOLFOX

STUDY DESIGN

- Retrospective electronic medical record review of patients who received FOLFOX cycle 1 day 1 from July 1, 2012 to December 1, 2014
  - Estimate inclusion of approximately 150 patients
  - Estimate approximately 10 to 20% received dexamethasone
- Inclusion criteria:
  - Patients 18 years of age or older
  - Patients who received FOLFOX at a LVHN infusion center
- Exclusion criteria:
  - Patients less than 18 years of age
  - Patients who received FOLFOX outside of a LVHN infusion center
- The following patient data will be collected: age, gender, body surface area, diagnosis, staging, surgery, chemotherapy doses, percentage of doses received, length of chemotherapy regimen, antiemetic regimen, other premedications, documented nausea, documented vomiting, hydration, documented hypersensitivity reactions

Nausea[7]

Grade	Description	Indication
Grade 0	None	No nausea
Grade 1	Loss of appetite	Nausea
Grade 2	Decreased oral intake	
Grade 3	Inadequate oral intake, tube feeding, TPN, hospitalization	

Vomiting[7]

Grade	Description	Indication
Grade 0	None	No vomiting
Grade 1	1 to 2 episodes in 24 hours	Vomiting
Grade 2	3 to 5 episodes in 24 hours	
Grade 3	>6 episodes in 24 hours, tube feeding, TPN, hospitalization	
Grade 4	Life threatening	
Grade 5	Death	

- Patients will be followed until completion of FOLFOX treatment
- Percentage of nausea, vomiting, and hypersensitivity reactions will be calculated overall and by cycle
- Percentage of patients with a RDI of 100% and average RDI will be calculated overall and by cycle

$$\text{RDI} = \frac{\text{Total Dose Delivered (\%)}}{\text{Total Weeks to Deliver FOLFOX Regimen}} \times \frac{100}{1.00 \text{ dose/24 weeks}}$$

- Depending on sample size, the average number of cycles patients at LVHN experienced nausea, vomiting, and hypersensitivity reactions will be compared between those who received dexamethasone and those who did not

Disclosure:

The authors have no financial or personal relationships to disclose with commercial entities that may have a direct or indirect interest in the subject matter of this presentation.

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