Children's Oncology Group

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Supportive Care Guidelines

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Supportive Care Guidelines

The following guidelines are provided for institutional consideration. Investigator discretion should be used and institutional considerations made for specific patient situations. Study Chairs should be notified of any Serious Adverse Events, an investigator's decision to deviate in a major way from protocol-directed therapy, or a patient taken off study. All such actions should be documented in the medical record and the case report forms.

Aggressive supportive care improves outcome, particularly in high-risk patient populations. The following guidelines are intended to give general direction for optimal patient care and to encourage uniformity in the treatment of patients on COG studies. Additional supportive care guidance may also be found in:

Altman, AJ, ed. *Supportive Care of Children with Cancer*. 3rd ed. Baltimore, MD: The Johns Hopkins University Press; 2004.

DIARRHEA

Diarrhea may be a result of damage to the cellular lining of the GI tract secondary to the administration of antineoplastic agents. Anti-metabolites, especially fluorouracil, and agents such as irinotecan, hematopoietic stem cell transplant, and abdominal or pelvic irradiation are most commonly associated with diarrhea.[2] Uncontrolled diarrhea can lead to serious fluid and electrolyte imbalances, contribute to the child's nutritional deficits and feelings of fatigue, and cause perianal skin breakdown.

General measures:
Avoid fatty, greasy foods, and limit intake of dairy products or consider the use of lactase or low-lactose milk products. Consume easy to digest carbohydrates such as rice, white bread and potatoes. Drink fluids frequently between meals to avoid dehydration (Gatorade®, bouillon, apple juice, gelatin, and grape juice). Avoid caffeinated drinks including soft drinks.

To prevent perianal skin breakdown clean the perianal area with mild soap and warm water after each loose bowel movement. Dry skin thoroughly and allow exposure to air as much as possible. Apply barrier cream such as A&D ointment or a zinc oxide containing ointments to dried area.

Diarrhea associated with Hematopoietic Stem Cell Transplant:
Apply general measures above and consider evaluation for infection (e.g.: clostridium difficile, CMV, cryptosporidium, etc.) and GI GVHD.

Diarrhea Secondary to Irinotecan
Patients who have the onset of diarrhea during the irinotecan infusion or in the several hours following completion of the irinotecan infusion should receive a dose of atropine (suggested dose 0.01 mg/kg IV, maximum dose 0.4 mg). Each family should be instructed to have antidiarrheal medication available and begin treatment at the first episode of poorly formed or loose stools or the earliest onset of bowel movements more frequent than normally expected for the patient. Patients should also be instructed to contact their physician if any diarrhea occurs.

Loperamide dosing recommendations for late diarrhea which occurs 8 hours after irinotecan (based on body weight):

Under 13 kg: Take 0.5 mg after the first loose bowel movement, followed by 0.5 mg every 3 hours. During the night, the patient may take 0.5 mg every 4 hours. Do not exceed 4 mg per day.

From 13 kg to less than 20 kg: Take 1 mg after the first loose bowel movement, followed by 1 mg every 4 hours. Do not exceed 6 mg per day.

From 20 kg to less than 30 kg: Take 2 mg after the first loose bowel movement, followed by 1 mg every 3 hours. During the night, the patient may take 2 mg every 4 hours. Do not exceed 8 mg per day.

From 30 kg to less than 43 kg: Take 2 mg after the first loose bowel movement, followed by 1 mg every 2 hours. During the night, the patient may take 2 mg every 4 hours. Do not exceed 12 mg per day.

->12 years old and adults: Take 4 mg after the first loose bowel movement, followed by 2 mg after each loose stool. Do not exceed 16 mg per day.

High dose loperamide (adults) 2mg every 2 hours

Failure of loperamide to control diarrhea within 24 hours of onset:
Begin subcutaneously or intravenously administered octreotide (Sandostatin®), 1-2 mcg/kg/dose every 12 hours. If needed, the dose may be titrated up to 10 mcg/kg/dose (maximum dose: 500 mcg) every 8 hours.

Antibiotics for GI Toxicities

For patients who develop Grade 3 or 4 gastrointestinal (GI) toxicity (see table below for the indications for antibiotic use) following irinotecan therapy, administration guidelines are provided for cefpodoxime (Vantin®) and cefixime (Suprax®).

Cefpodoxime: 10 mg/kg/day, divided in 2 oral doses; maximum daily dose 400 mg for children < 12 years and maximum daily dose 800 mg for those ≥ 12 years)

or

Cefixime: (8 mg/kg/dose as a single daily oral dose or divided BID; maximum daily dose 400 mg).

The antibiotic should be started 5 days prior to the start of irinotecan therapy only if the patient experienced Grade 3 or 4 colitis, dehydration, diarrhea, abdominal pain, weight loss or vomiting during prior therapy with irinotecan. If it is not feasible to start cefpodoxime or cefixime 5 days prior to therapy with irinotecan, give at least 1 full day of cefpodoxime or cefixime prior to the start of irinotecan course. Refer to institutional guidelines for administration.

Indications for Antibiotic Use (Cefpodoxime or Cefixime) for GI Toxicities Due to Irinotecan

Toxicity	Defined as
Abdominal Pain	Severe pain, pain or analgesics severely interfering with activities of daily living, disabling.
Colitis (Grade 3 or 4)	Abdominal pain, fever, change in bowel habits with ileus or peritoneal signs, and radiographic or biopsy documentation of perforation or requiring surgery or toxic megacolon.
Dehydration	Requiring IV fluid replacement (sustained), physiologic consequences requiring intensive care, hemodynamic collapse.
Diarrhea	Increase of $\geq$ 7 stools/day or incontinence; or need for parenteral support for dehydration, severe increase in loose stool, physiologic consequences requiring intensive care, hemodynamic collapse, or watery stool output compared with pretreatment, interfering with normal activity, physiologic consequences requiring intensive care, hemodynamic collapse.
Vomiting	$\geq$ 6 episodes in 24 hours over pretreatment, or need for IV fluids requiring parenteral nutrition, or physiologic consequences requiring intensive care, hemodynamic collapse.
Weight Loss	> 20%

Adapted from[7] Perry MC et al., ed. *Companion Handbook to Chemotherapy Source Book.* 2nd ed. Baltimore, MD: Lippinkott, Williams and Wilkins; 2004.