

BCCA Protocol Summary for Palliative Chemotherapy for Upper Gastrointestinal Tract Cancer (Gastric, Esophageal, Gall Bladder, Pancreas Carcinoma and Cholangiocarcinoma) and Metastatic Anal using Infusional Fluorouracil and Cisplatin

Protocol Code
Tumour Group
Contact Physician

GIFUC
Gastrointestinal
GI Systemic Therapy

ELIGIBILITY:

- Metastatic or unresectable adenocarcinoma of the upper gastrointestinal tract (stomach, esophagus, gall bladder, pancreas, bile ducts)
- Metastatic squamous cell or cloacogenic carcinoma of the anal canal
- ECOG 0-2

EXCLUSIONS:

- CNS metastases
- Uncontrolled high blood pressure, unstable angina, symptomatic congestive heart failure, myocardial infarction within the preceding 6 months, serious uncontrolled cardiac dysrhythmia
- Inadequate hepatic function (total bilirubin >35µmol/L, AST >3x normal)
- Inadequate renal function (creatinine clearance less than 45 ml/min as calculated by Cockcroft/Gault formula – see page 3)

TESTS:

- Baseline: CBC, diff and platelets, creatinine
- Before each treatment: CBC, diff and platelets, creatinine
- If clinically indicated: bilirubin, appropriate imaging studies

PREMEDICATIONS:

This regimen is high moderate in emetogenic potential. See SCNAUSEA protocol.

TREATMENT:

Drug	Dose	BCCA Administration Guideline
Cisplatin	25 mg/m ²	IV in 100 mL NS over 20-30 min
Fluorouracil (5FU)	1000 mg/m ² /day for 2 days (total dose = 2000 mg/m ² over 48 h) Maximum dose = 5000 mg/48 h	IV in D5W to a total volume of 96 mL by continuous infusion at 2 mL/h via appropriate infusor device*

*For total dose > 4600 mg, to a total volume of 240 mL by continuous infusion at 5 mL/h.

(Inpatients: 1000 mg/m²/day in 1000 mL D5W by continuous infusion daily over 24 h for 2 days)

Patients with PICC lines should have a weekly assessment of the PICC site for evidence of infection or thrombosis.

Repeat every 7 days for 12 cycles (maximum = 24 cycles). Most responding patients will manifest benefit by 6-8 cycles.

DOSE MODIFICATIONS:

1. Hematological:

ANC (x10 ⁹ /L)		Platelets (x10 ⁹ /L)	Dose (both drugs)
≥ 1.0	and	≥ 100	100%
< 1.0	or	< 100	delay

2. Renal dysfunction:

Delay for one week if serum creatinine >3 x ULN. If serum Creatinine <3 x ULN adjust cisplatin dose as follows:

Creatinine Clearance (by Cockcroft/Gault formula)	Dose - Cisplatin only
> 60 ml/min	100%
45 – 59 ml/min	50%
< 45 ml/min	delay

Cockcroft/Gault formula:

$$CrCl = \frac{N (140-age) \times weight (kg)}{serum creatinine (\mu mol/L)}$$

Where N = 1.04 for females, and 1.23 for males

3. Gastrointestinal toxicity:

Grade	Stomatitis	Diarrhea	Dose Fluorouracil
Grade 1	Painless ulcers, erythema or mild soreness	Increase of 2-3 stools/day or nocturnal stools; or moderate increase in loose watery colostomy output	100%
Grade 2	Painful erythema, edema, or ulcers but can eat	Increase of 4-6 stools/day, or nocturnal stools or moderate increase in loose watery colostomy output	75%
Grade 3 or 4	As above, but cannot eat, mucosal necrosis, requires parenteral support.	Increase of greater than 7 stools/day or grossly bloody diarrhea, or incontinence, malabsorption; or severe increase in loose watery colostomy output requiring parenteral support	Discontinue or delay until toxicity resolved then resume at 50%.

4. Hand-Foot Syndrome

Grade	Hand-Foot Syndrome	Dose Fluorouracil
Grade 1	Skin changes or dermatitis without pain e.g. erythema, peeling	100%
Grade 2	Skin changes with pain not interfering with function	75% until resolved then consider increasing dose by 10%
Grade 3	Skin changes with pain, interfering with function	Delay until resolved then resume at 75%

5. Hepatic dysfunction: Omit treatment if bilirubin >85 umol/L unless secondary to biliary obstruction. Refer to BCCA Cancer Drug Manual.

PRECAUTIONS:

1. **Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.
2. **Renal Toxicity:** Nephrotoxicity is common with cisplatin. Encourage oral hydration. Avoid nephrotoxic drugs such as aminoglycoside antibiotics.
3. **Myocardial** ischemia and angina occurs rarely in patients receiving Fluorouracil. Development of cardiac symptoms including signs suggestive of ischemia or of cardiac arrhythmia is an indication to discontinue treatment.

Call the GI Systemic Therapy physician at your regional cancer centre or Dr. Hagen Kennecke at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

Date activated: N/A

Date revised: 01 Mar 2008 ([administration of fluorouracil infusion revised](#))