BC Cancer Agency

Systemic Therapy Update

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Website access at http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate.htm

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EDITOR'S CHOICE

DRUG UPDATE

Newly Marketed Drugs Health Canada has recently granted conditional approval of two new oral tyrosine kinase inhibitors, **sorafenib** (NEXAVAR®) and **sunitinib** (SUTENT®). Both drugs have been approved for the treatment of locally advanced/metastatic renal cell carcinoma for patients whose disease has progressed on prior cytokine therapy or who are considered unsuitable for such therapy. In addition, sunitinib has also been approved for gastrointestinal stromal tumour (GIST) after progression on imatinib treatment due to intolerance or resistance. Currently, sorafenib and sunitinib are not on the benefit list of the BC Cancer Agency. Details on compassionate access to these drugs are on the BC Cancer Agency website (www.bccancer.bc.ca/HPI/ChemotherapyProtocols/sapchart).

Sorafenib and sunitinib both target multiple receptors, including the vascular endothelial growth factor (VEGF), platelet-derived growth factor (PDGF), and c-kit. In clinical trials, sorafenib has been shown to improve progression-free survival compared to placebo in patients with progressive renal cell carcinoma. Sunitinib has been associated with partial response in single-arm trials with similar patients. In addition, sunitinib has been shown to prolong time to tumour progression in patients with imatinib-resistant GIST.

CANCER DRUG MANUAL

Cyclophosphamide Monograph Dosing in patients with renal failure has been clarified in the Dosage Guidelines section.

Docetaxel Monograph Information on previous formulation has been removed in the Parenteral Administration section.

Topotecan Monograph Information on the Interaction table has been corrected.

CANCER MANAGEMENT GUIDELINES

Bisphosphonate Treatment of Multiple Myeloma To minimize the risk of osteonecrosis (of the jaw) and renal toxicity, the duration of pamidronate treatment has been limited to 24 months. This was the time shown to be beneficial in the randomized trial. After 24 months, pamidronate should be stopped and only resumed for another 24-month course if the myeloma again requires systemic treatment. (see List of Protocol Changes under MYPAM)

Hepatitis B Reaction in Lymphoma Patients Treatment with lamivudine has been extended to include the entire duration of the systemic treatment and for six months afterwards (previously two months). This applies to patients found to have positive testing for either hepatitis B surface antigen (HBsAg) or antibody to hepatitis B core antigen (HBcoreAb). These patients are considered to be at risk for fulminant hepatitis, if treated with immunosuppressive chemotherapy regimens, especially those including corticosteroids or purine analogues, and including monoclonal antibodies such as rituximab. (see Highlights of Protocol Changes).

HIGHLIGHTS OF PROTOCOL CHANGES

Lymphoma Protocols using immunosuppressive chemotherapy, particularly corticosteroids, purine analogues, and monoclonal antibodies have been revised to extend the duration of lamivudine treatment for patients tested positive with either HBsAg or HBcoreAb (see Cancer Management Guidelines and List of Protocol Changes).

FOCUS ON: FLUOROURACIL – FACTORS AFFECTING TOXICITY

Fluorouracil (5-FU) is a chemotherapeutic agent which is used in the treatment of many types of cancer. It has been available for many years and has become familiar to most oncology practitioners. Side effects most often include myelosuppression, diarrhea, stomatitis, and palmar-plantar erythrodysesthesia (PPE, or hand-foot syndrome). Dosage adjustments for these toxicities are outlined in BC Cancer Agency protocols. Cardiac, ocular, dermatologic and neurologic toxicities may also rarely occur and are described in the Cancer Drug Manual fluorouracil monograph.

It is important to remember that fluorouracil toxicity can be affected by many factors. Dosing factors such as administration methods and dosing schedules may predict different toxicities. Patient factors such as age, gender, and dihydropyrimidine dehydrogenase (DPD) deficiency may also play a role. With the variety of treatment schedules available, increased vigilance is required to ensure the correct dosage is received by the patient and that relevant toxicities are closely monitored.

Dosing factors

Administration

Fluorouracil is given in many different dosages depending on the disease, response and concomitant therapy. It may be given by IV bolus, continuous infusion, or both routes may be used within a single protocol. It is imperative to confirm the dosage and route before administering the fluorouracil to avoid inadvertent confusion of bolus and continuous infusion doses. Fatalities have occurred when the dose meant for continuous infusion was given as a bolus.

Effect of dosing schedule on pharmacokinetics

The pharmacokinetic profile of fluorouracil varies according to dose and schedule and may impact toxicity. The terminal half-life after IV bolus administration is 14 minutes at conventional doses, but at higher doses clearance follows non-linear pharmacokinetics due to saturable degradation and the half-life has been noted up to five hours. Therefore, the nonlinear pharmacokinetics results in unpredictable plasma concentrations and toxicity at high doses. The clearance of fluorouracil is faster with continuous infusion and increases as the dose rate decreases. The concentration in bone marrow is lower after continuous infusion than after IV bolus dosing, which is consistent with the decreased myelotoxicity of continuous infusion schedules.[1]

Effect of dosing schedule on clinical toxicity

Fluorouracil is administered in many different dosing schedules and with other treatment modalities which affect its toxicity profile. For example, with daily bolus administration of fluorouracil for 5 days, diarrhea is the most frequent dose-limiting effect and myelosuppression is often more significant than with continuous IV infusion regimens. In contrast, the incidence of PPE is higher with continuous infusion regimens.[1]

The following table illustrates some of the differences in toxicities found with various treatment regimens[1-3]:

5-FU Dosing Schedule (regimen name)	5-FU Dose	Primary Dose-Limiting Toxicities	Other Significant Toxicities
IV bolus q 3-4 weeks[4] (Roswell-Park)	e.g., 500-600 mg/m^2	myelosuppression diarrhea	stomatitis
daily IV bolus x 5 days q 4 weeks[5] (Mayo)	e.g., 425 mg/m^2	diarrhea stomatitis	myelosuppression
continuous IV infusion[6]	e.g.,1000 mg/m^2/24 h x 48 h	diarrhea stomatitis	PPE myelosuppression
continuous IV infusion concurrent with radiation[7]	e.g., 225 mg/m^2/24 h during radiation	myelosuppression	diarrhea stomatitis PPE
IV bolus plus infusion q 2 weeks[8] (de Gramont)	e.g., 400 mg/m^2 followed by 2400 mg/m^2 over 46 h	myelosuppression	diarrhea stomatitis

The clinical toxicity associated with 5-FU given by either bolus or continuous infusion in patients with metastatic colorectal cancer was compared in a meta-analysis based on 1219 patients from six randomized trials.[9] The incidence of Grade 3 to 4 hematologic toxicity was significantly higher for the bolus group (31% vs. only 4%). The risk of all grades of hand-foot syndrome was found to be significantly higher in the continuous infusion group (34% vs. 13%). Of note, three toxic deaths were reported in each group. In this study, the risk of severe diarrhea, nausea/vomiting, or mucositis was not significantly different between the groups: 13% for the continuous infusion group and 14% for the bolus group. In a subsequent French intergroup study, the bolus Mayo schedule was compared with the 48-hour high-dose biomodulated infusion schedule of 5-FU (de Gramont).[10] The infusional schedule was associated with less neutropenia (2% vs. 7%), diarrhea (3% vs. 7%) and mucositis (2% vs. 13%).

Patients receiving concurrent radiation or who have had previous high dose pelvic radiation often require lower doses due to additive bone marrow suppression,[11] and indeed fatalities have occurred when the dose was not reduced in conjunction with radiation.

Patient factors

Age

Age is an independent risk factor for 5-FU toxicity.[1] A prospective randomized trial of 5-FU treatment for advanced colorectal cancer was analyzed for toxicities using age less than 70 years vs. 70 years or older.[12] Advanced age was associated with the significant occurrence of any severe toxicity (58% vs. 36%), leucopenia (24% vs. 10%), diarrhea (24% vs. 14%), vomiting (15% vs. 5%), and treatment mortality (9 % vs. 2%).

Gender

In a study which analyzed the results of 4 trials and 1074 patients with colorectal cancer for gender differences in the toxicity of 5-FU treated patients, a significant difference was seen in the toxicities for women.[13] Women had a greater average maximum toxicity grade, a greater number of different types of toxicities experienced, and a higher incidence of severe toxicities. The incidence of Grade 2 or greater hematologic toxicity was higher in women and they experienced more frequent moderate to severe mucositis than men. These differences were seen across various treatment regimens and patient characteristics.[13]

DPD deficiency

This may result in life-threatening or fatal toxicity in patients receiving 5-FU via parenteral or even topical administration.[2] The frequency of low or deficient DPD activity in Caucasian and African-American populations is 3-5% and 0.1% respectively.[14] 5-FU clearance is dependent on DPD as 5-FU is enzymatically inactivated to dihydrofluorouracil by DPD.[15] Tests for the diagnosis of DPD deficiency are not readily available and as a result most cases are diagnosed after an unexpected degree of toxicity is observed following the administration of 5-FU.[1]

Summary

Expected toxicities of 5-FU are dependent on the dose, schedule and route of administration and may be affected by individual patient characteristics including age, gender and DPD deficiency.

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LIST OF NEW AND REVISED PROTOCOLS

The **BC Cancer Agency Protocol Summaries** are revised on a periodic basis. New and revised protocols for this month are listed below. Protocol codes for treatments requiring "Undesignated Indication" approval are prefixed with the letter **U**.

Revised protocols:

Code	Changes	Protocol Name
BRAVTR	*Blood work requirements prior to treatments revised*	Palliative Therapy for Metastatic Breast Cancer Using Trastuzumab
LYABVD	*Duration of lamivudine treatment extended*	Treatment of Hodgkin's disease with Doxorubicin, Bleomycin, Vinblastine and Dacarbazine
ULYALEM	*Duration of lamivudine treatment extended*	Treatment of Fludarabine-Refractory B-Chronic Lymphocytic Leukemia (B-CLL) and T-Prolymphocytic Leukemia (T-PLL) with Alemtuzumab
LYCDA	*Duration of lamivudine treatment extended*	Treatment of Hairy Cell Leukemia with Cladribine
LYCHLOR	*Duration of lamivudine treatment extended*	Therapy for Low Grade Lymphoma and Chronic Lymphocytic Leukemia Using Chlorambucil
LYCHOP	*Duration of lamivudine treatment extended*	Treatment of Lymphoma with Doxorubicin, Cyclophosphamide, Vincristine and Prednisone
LYCHOPR	*Duration of lamivudine treatment extended*	Treatment of Lymphoma with Doxorubicin, Cyclophosphamide, Vincristine, Prednisone and Rituximab
LYCSPA	*Duration of lamivudine treatment extended*	Cyclosporine for cytopenias associated with lymphoproliferative disorder of large granular lymphocytes
LYCVP	*Duration of lamivudine treatment extended*	Advanced Indolent Lymphoma using Cyclophosphamide, Vincristine and Prednisone
LYCVPPABO	*Duration of lamivudine treatment extended*	Treatment of Hodgkin's Disease with Cyclophosphamide, Vinblastine, Procarbazine And Prednisone
LYCVPR	*Duration of lamivudine treatment extended*	Treatment of Advanced Indolent Lymphoma using Cyclophosphamide, Vincristine, Prednisone and Rituximab (CVP-R)
LYCYCLO	*Duration of lamivudine treatment extended*	Therapy of Lymphoma, Hodgkin's Disease, Chronic Lymphocytic Leukemia or Multiple Myeloma Using Cyclophosphamide
LYECV	*Duration of lamivudine treatment extended*	Consolidation for Lymphoma Using Etoposide and Cyclophosphamide
LYFLU	*Duration of lamivudine treatment extended*	Treatment of Low-Grade Lymphoma or Chronic Lymphocytic Leukemia with Fludarabine
LYFLUDR	*Duration of lamivudine treatment extended, administration schedule for PO and IV fludarabine revised*	Treatment of Chronic Lymphocytic Leukemia or Prolymphocytic Leukemia with Fludarabine and Rituximab
LYGDP	*Duration of lamivudine treatment extended*	Treatment of Lymphoma with Gemcitabine, Dexamethasone and Cisplatin (GDP)

Code	Changes	Protocol Name
LYHDMTXP	*Duration of lamivudine treatment extended*	Treatment of Primary Intracerebral Lymphoma with High Dose Methotrexate
LYHDMTXR	*Duration of lamivudine treatment extended*	Treatment of Leptomeningeal Lymphoma or Recurrent Intracerebral Lymphoma with High Dose Methotrexate
LYIT	*Duration of lamivudine treatment extended*	Treatment of Lymphoma using Intrathecal Methotrexate and Cytarabine
ULYMFBEX	*Duration of lamivudine treatment extended and Tests revised*	Treatment for refractory cutaneous T-cell lymphoma using Bexarotene (Note: approval from the Health Canada Special Access Programme required)
ULYMFECP	*Hepatitis B reactivation management added*	Treatment of Cutaneous T-cell Lymphoma (Sézary syndrome) with Extracorporeal Photopheresis
LYPALL	*Duration of lamivudine treatment extended*	Lymphoma Palliative Chemotherapy
ULYRICE	*Duration of lamivudine treatment extended*	Treatment of Advanced Stage Large B-Cell Non-Hodgkin's Lymphoma with Ifosfamide, Carboplatin, Etoposide and Rituximab
LYRITB	*Duration of lamivudine treatment extended, restriction to Vancouver Centre deleted*	Summary for Palliative Therapy For Lymphoma Using Radioimmunotherapy: Tositumomab-Priming for I^{131} Tositumomab
LYRITUX	*Duration of lamivudine treatment extended, standard CBC panel tests clarified*	Treatment of Lymphoma with Single Agent Rituximab
LYRITZ	*Duration of lamivudine treatment extended*	Palliative Therapy For Lymphoma Using Radioimmunotherapy: Rituximab-Priming for Ibritumomab ^{90}Y
ULYRMTN	*Duration of lamivudine treatment extended*	Maintenance Rituximab for Indolent Lymphoma
LYSNCC	*Duration of lamivudine treatment extended*	Treatment of Burkitt lymphoma with Cyclophosphamide and Methotrexate (Leucovorin)
UMYBORTEZ	*Duration of lamivudine treatment extended*	Treatment of Multiple Myeloma with Bortezomib
MYMP	*Duration of lamivudine treatment extended, baseline tests revised*	Treatment of Multiple Myeloma Using Melphalan and Prednisone
MYPAM	*Osteonecrosis warning added, treatment duration revised*	Treatment of Multiple Myeloma with Pamidronate
UMYTHALID	*Duration of lamivudine treatment extended, typo corrected in reference*	Therapy of Multiple Myeloma Using Thalidomide

PROTOCOL-SPECIFIC PATIENT HANDOUTS

The **BC Cancer Agency Protocol-Specific Patient Handouts** are developed and revised on a periodic basis. New handouts for this month are listed below.

Revised protocols:

Code	Changes	Protocol Name
BRAJTR	*New*	Adjuvant Therapy for Breast Cancer using Trastuzumab following the Completion of Chemotherapy (Sequential)
BRAVNAV	*New*	Palliative therapy for symptomatic metastatic breast cancer using Vinorelbine
BRAVTR	*New*	Palliative Therapy for Metastatic Breast Cancer Using Trastuzumab
BRAVTRNAV	*New*	Palliative therapy for metastatic breast cancer using trastuzumab and vinorelbine

LIST OF NEW AND REVISED PRE-PRINTED ORDERS

The **INDEX to BC Cancer Agency Pre-printed Orders** are revised on a periodic basis. The revised pre-printed orders for this month are listed below.

Revised pre-printed orders:

Code	Changes	Pre-Printed Order Name
BRAVTR	*Blood work requirements prior to treatments revised*	Palliative Therapy For Metastatic Breast Cancer Using Trastuzumab
BRLAACD	*Baseline labs clarified*	Treatment Of Locally Advanced Breast Cancer Using Doxorubicin And Cyclophosphamide Followed By Docetaxel And Trastuzumab
LYFLUDR	*Administration schedule for PO and IV fludarabine revised*	Treatment of Chronic Lymphocytic Leukemia or Prolymphocytic Leukemia with Fludarabine and Rituximab

CONTINUING EDUCATION

International Conference for Cancer Nursing (ICCN) The Canadian Association of Nurses in Oncology (CANO) and the International Society of Nurses in Cancer Care (ISNCC) will cohost the 14th ICCN on **27 September** to **1 October, 2006**, at the Sheraton Centre in Toronto, Ontario. The ICCN is the largest international meeting of cancer nurses and the theme for this year is *"Reaching New Heights Together"*.

Conference information and registration forms are available on the CANO website at www.cos.ca/cano.

National Oncology Pharmacy Symposium (NOPS) 2006 will be held from **13-15 October, 2006** at the Hyatt Regency in Marriott Bloor-Yorkville in Montréal, Quebec. The theme for 2006 is *"The Dollars and Sense of Quality Cancer Care"*. This symposium is presented by the Canadian Association of Pharmacy in Oncology (www.capho.org).

Registration is now open and can be submitted online (www.meetingassistant.com/NOPS2006.). Early registration rates will end by September 15, 2006 and online registration will close on October 10, 2006.

BC Cancer Agency Annual Cancer Conference 2006 You can now register for this year's conference, which will be held from **23-25 November, 2006** at the Westin Bayshore Resort and Marina in Vancouver.

Registration fees are: $125 early bird (before 29 September), $175 (after 29 September through 23 November) and $200 onsite (23-25 November).

The theme of this year will be **"***Partners in Research and Care – BC & the World***",** which will create the framework for the exploration of how the BC Cancer Agency encourages collaboration between researchers, scientists, clinicians and community resource professionals, within the provincial system of cancer control, as well as with organizations around the world.

The *Partners in Cancer Care* meeting and the BC Cancer Agency Research Centre *Scientific Meeting* will be held respectively on Thursday, 23 November. The *Clinical Scientific Symposium* will be held on Friday, 24 November. This is open to all healthcare professionals and is an academic, evidence-based exploration of new scientific insights that hold potential to advance cancer care. In addition, there will be *Provincial Oncology Professionals* education and business meetings held on selected dates (preliminary) on 23-25 November for the following disciplines:

Thursday, 23 November
- Oral Oncology
- Psychosocial Oncology

Friday, 24 November
- Nutrition
- Palliative Care

Saturday, 25 November
- Pharmacy
- Nursing
- Surgical Oncology
- Medical Oncology
- Radiation Therapy
- Family Practice
- Pediatric Oncology

Other programs will include the *Poster Presentation and Awards Banquet* (24 November) and the *Community Cancer Forum* (25 November).

For more information on the conference registration, please visit the BC Cancer Agency website www.bccancer.bc.ca.

WEBSITE RESOURCES

The following are available on the BC Cancer Agency website (www.bccancer.bc.ca) under the Health Professionals Info section:

Reimbursement and Forms: Benefit Drug List, Class II, Compassionate Access Program (Undesignated Indication)	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms
Cancer Drug Manual	www.bccancer.bc.ca/cdm
Cancer Management Guidelines	www.bccancer.bc.ca/CaMgmtGuidelines
Cancer Chemotherapy Protocols	www.bccancer.bc.ca/ChemoProtocols
Cancer Chemotherapy Pre-Printed Orders	www.bccancer.bc.ca/ChemoProtocols under the index page of each tumour site
Systemic Therapy Program Policies	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies
Unconventional Cancer Therapies Manual	under Patient/Public Info, Unconventional Therapies

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