Monoclonal antibodies (MoAbs) are targeted therapies that have a unique set of infusion-related complications. A new weapon in the MoAb armory that received U.S. Food and Drug Administration (FDA) approval in May 2001 is Campath® (alemtuzumab, Berlex Laboratories, Richmond, CA). Campath is indicated for the treatment of B cell chronic lymphocytic leukemia (CLL) in patients who have been treated with alkylating agents and who have not responded to fludarabine therapy (Millennium and ILEX Partners, 2001). In addition to causing intense infusion reactions, Campath severely suppresses the immune system, which leaves patients vulnerable to infection. MoAb therapy, such as Campath, is administered routinely in the outpatient setting. Administration and management of side effects in the ambulatory setting is a challenge for nurses.

Overview of Campath

CLL traditionally has been considered an indolent, incurable disease of the elderly characterized by periods of remission and eventual relapse or progression. Historically, treatment regimens have included alkylating agents with or without steroids (Byrd, Rai, Sausville, & Grever, 1998). Recently, fludarabine has emerged as the treatment of choice for untreated or treatment-refractory patients (Rai, 1999). Although disease response has improved with fludarabine, new therapeutic strategies are required to increase survival for patients with CLL (Dyer, 1999). A new agent showing promise in the treatment of CLL is Campath. Pivotal study results (Keating et al., 1999) demonstrated an overall response rate of 33% from Campath in heavily pretreated patients with CLL and led to its FDA approval.

Campath is a humanized MoAb that is directed against the cell surface antigen CD52. CD52 is expressed on normal and malignant B and T lymphocytes. The mechanism of action is thought to be lysis of leukemic cells following cell surface binding. The recommended dosing schedule includes an initial dose escalation from 3 mg to 10 mg to a plateau dose of 30 mg. Patients first are given 3 mg IV over two hours daily until they are able to tolerate the medication without an infusion reaction. The dose then is escalated to 10 mg IV over two hours daily until tolerated without infusion reaction. Finally, the drug is escalated to 30 mg IV over two hours three times per week for up to 12 weeks.

Flynn and Byrd (2000) published a comprehensive review of several Campath clinical trials. Their data synthesis not only highlighted the efficacy of Campath in CLL, but discussed treatment toxicities, notably infusion-related events and infection. Infusion reactions included a symptom complex of fever and rigors (any grade) that occurred in more than 80% of patients during dose escalation. According to the Campath drug package insert (Millennium and ILEX Partners, 2001), 16% of patients experienced National Cancer Institute Common Toxicity Criteria grade 3 or higher rigors (requiring meperidine) and 19% experienced rigors and/or fever (≥ 104°F for ≥ 24 hours). These acute reactions are thought to be related to cytokine release during drug administration and generally resolve as patients reach the plateau dose. However, when these symptoms occur, patient comfort and safety are paramount. Premedication regimens with acetaminophen and diphenhydramine are essential to minimize the incidence of infusion events. The availability of meperidine, corticosteroids, epinephrine, and other emergency measures also are important considerations when planning care.

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Karen Seeley, RN, BSN, OCN®, and Elaine DeMeyer, RN, MSN, AOCN®
Infection is the most significant complication of Campath therapy. Opportunistic infection risk is high because of profound and rapid lymphopenia. In one early study, mean CD4+ counts measured after just four weeks of Campath were 18 x 10^3/µL and began to normalize at 16 weeks (Rai et al., 1995). Viral, fungal, and bacterial infections are common, especially in heavily pretreated patients (Osterborg et al., 1997). Prophylaxis against protozoal and viral infections is standard preventative care. A regimen of trimethoprim/sulfamethoxazole DS 1 administered twice daily (bid) three times per week and foscarnet 250 mg bid is recommended at initiation of Campath therapy and may be continued for at least two months after completion of therapy. Additionally, consideration should be given to antifungal protection in patients with a previous history of known fungal infection. Patients with this risk factor may be given a daily regimen of itraconazole or fluconazole in addition to their other anti-infective medications. Healthcare professionals must take the patients’ allergy histories into account when prescribing these medications and give substitutions as appropriate.

Other toxicities occurring at frequencies in excess of 30% include neutropenia (85%), anemia (80%), thrombocytopenia (72%), nausea (54%), vomiting (41%), rash (40%), fatigue (34%), and hypotension (32%) (Memorial and ILEX Partners, 2001). With the exception of pancytopenia and fatigue, all are drug infusion related. Rashes are treated with additional administration of IV antihistamines and/or corticosteroids. Hypotension usually resolves by interrupting the Campath infusion and administering an IV fluid bolus. Fatigue, nausea, vomiting, and pancytopenia are endemic to cytotoxic therapy, and the usual support and symptom relief measures apply.

**Patient Population**

Because of the toxicities associated with Campath, the potential physiologic limitations that patients with CLL have at baseline must be considered. Although CLL often is diagnosed in patients less than 55 years of age, it is most commonly considered a disease of the elderly (De Lima, O’Brien, Lerner, & Keating, 1998). Advanced age coupled with prior treatment for CLL places patients at risk for immune system compromise prior to initiation of Campath. Often, these patients also have concomitant medical problems, such as hypertension or cardiac or renal insufficiency, which may necessitate alterations to the required hydration for Campath.

Campath therapy requires a grueling treatment schedule that often is different from prior cancer therapies patients may have received. Daily drug administration during the dose escalation phase and then administration three times per week for up to 12 weeks is a significant time and resource demand for patients. Transportation needs alone may present quite an obstacle. Campath treatment is held for grade 3 or 4 toxicity. If held for more than seven days, dose reescalation is required from 3 mg to 10 mg to 30 mg as in the beginning because of the risk of infusion events. The prophylactic and empiric anti-infective therapy and other support medications not only present additional financial burdens but also require vigilant compliance.

**Challenges in Ambulatory Oncology Nursing**

The most notable challenges in ambulatory oncology nursing are time, setting, staffing, and continuity of care. The chronic, multisystem nature of cancer makes it difficult to manage, especially during periods of intense treatment (e.g., MoAb therapy). These concerns are not unique to the care of patients receiving Campath. Multiple authors have addressed these challenges and offered guidance in their management (Cooley, Lin, & Hunter, 1994; Walter & Robinson, 1994). As succinctly stated by Farrell et al. (1998), “the challenge is to provide the right care, to the right client, in the most appropriate setting, using the most appropriate provider, with the most cost effective nursing care” (p. 73). Ambulatory oncology nurses and nurse managers are encouraged to be mindful of these issues when planning care for patients receiving MoAb therapy, particularly Campath with its complex regimen and side effects.

**Time**

Nurses in ambulatory settings do not provide around-the-clock care to patients. Typically, centers operate between 8–12 hours per day, with a core team of staff working typical full workdays. This necessitates the practice of “planning care for patients receiving MoAb therapy,” particularly Campath with its complex regimen and side effects.
per day and do not include weekends or holidays. The option of prioritizing nursing interventions by shift over a 24-hour period may not exist in the ambulatory setting. The complex care needed by acutely ill patients with cancer must be addressed within the limited hours of center operation. Patients receiving Campath therapy may be required to spend four to eight hours per day in treatment at a care center. Therapy must fit into patients’ daily schedules with consideration given to their energy levels and dependence on others for transportation, as well as staying on track with the Campath regimen.

Setting

The definition of the word ambulatory, “walking about or able to walk about” (Stedman, 1995, p. 57), has great implications for the level of care provided. Patients with mobility impairment may have difficulty with simple tasks, such as getting to the bathroom during a lengthy infusion therapy. Ambulatory care settings include office practices, clinics, and larger freestanding centers and, consequently, may have different levels of emergency preparedness. Some are better able and equipped to handle medical emergencies than others. These issues are important to address when considering Campath therapy.

Staffing

The appropriate levels of care that providers need to meet the demands of the complex oncology ambulatory care workload must be determined. Medvec (1994) identified the difficulty in developing a system to assess staff productivity in ambulatory care because of the number of variables in this setting. When administering Campath, nursing staff must be aware of potential infusion complications and be able to safely manage their patients’ care.

Continuity of Care

Although many definitions and descriptions of continuity of care appear in the literature, Bedder and Aikin (1994) summarized it as a philosophy and standard of care that involves patients, families, and healthcare providers working together to provide a comprehensive continuum of care. A stringent need is present for cooperation and communication among patients, caregivers, and healthcare teams to minimize complications from Campath therapy. Only part of the therapy is managed in the healthcare setting; the anti-infective regimens and symptom monitoring occur at home. Patients also must adhere to complex medication schedules. Patients and caregivers must feel confident and connected to their healthcare team to promptly report any sign of infection.

Nursing Care

A standard, systematic approach is required to meet the numerous challenges of ambulatory oncology nurses caring for patients receiving Campath. The approach can be divided into three phases: pretreatment planning, patient education, and treatment.

Pretreatment Planning

An assessment of the ambulatory care setting where Campath is administered is the first challenge prior to initiation of therapy. Priorities of this assessment include

• Comfortable facilities for patients as they will require lengthy treatment stays

1. Verify patient is taking anti-infective prophylaxis.
   ___ Trimethoprim/sulfamethoxazole DS 1 twice daily (bid) three times per week
   ___ Famciclovir 250 mg bid
   ___ Antifungal prophylaxis as ordered
   ___ Allopurinol as ordered

2. Begin mainline IV fluid normal saline (NS) at 500 cc/hour for one hour. Begin monitoring vital signs (i.e., pulse, blood pressure, and arterial blood oxygen saturation) every 15 minutes.

3. After 30 minutes of hydration, give**
   • Acetaminophen 650 mg po
   • Diphenhydramine 50 mg IV
   • Meperidine 25 mg IV*

4. Have available at chair side
   • Meperidine injectable*
   • Hydrocortisone 100 mg injectable
   • Epinephrine 1:1,000 injectable
   • Diphenhydramine 50 mg injectable

5. After one hour of pretreatment and pretreatments are given, begin Campath® 1H (Berlex Laboratories, Richmond, CA) infusion.
   ___ mg in 100 cc NS IV piggyback to infuse over two hours via rate-controlled infusion pump.
   • Reduce main line IV fluid rate to keep vein open during Campath infusion. The physician must be notified when the Campath infusion is started during ramp-up dosing.

6. Stop infusion if any of the following indications of infusion reaction occur.
   • Hypotension (systolic blood pressure [SBP] < 90 or a decrease of > 10 mm Hg from baseline if baseline SBP < 90)
   • Signs (rigors, fever, oxygen desaturation)
   • Symptoms (dyspnea, back pain, pruritis, restlessness or other subjective complaints)

7. Treat infusion reactions as follows.
   • Hypotension: Increase main IV fluid rate to bolus 250 cc in 30 minutes. Notify physician.
   • Rigors: Meperidine* 25 mg IV, repeat in 15 minutes. If no relief is achieved, notify physician.
   • Fever: Acetaminophen 650 mg po
   • Dyspnea, back pain, pruritis, oxygen desaturation: Hydrocortisone 100 mg IV (± epinephrine 1:1,000, 0.3 cc subcutaneous, ± diphenhydramine 25–50 mg IV), notify physician.

8. If infusion reaction symptoms completely resolve and the patient is back to baseline, the nurse may rechallenge with Campath 1H with the physician’s order.

9. If an infusion reaction occurs during rechallenge, treat as above (in item #7) and discontinue further infusions with Campath 1H for the day.

10. If unable to complete dose as ordered, the nurse must repeat at same dose level daily until tolerated before increasing to next dose level. Add hydrocortisone 100 mg IV to daily premedications for all subsequent infusions.

11. The post-Campath infusion hydration with a minimum of 250 cc NS is administered over one to two hours.

FIGURE 2. ARCH MEDICAL GROUP STANDING ORDERS FOR CAMPATH® 1H INFUSION

Note. Adapted with permission from the Arch Medical Group.
*If the patient has true allergy to meperidine, lorazepam IV may be substituted for premedication and treatment of rigors.
**Premedication with meperidine is needed only during dose ramp-up, not if on stable dosing three times per week.
**Figure 3. Arch Medical Group CamPATH® Treatment Record**

Note. Figure courtesy of the Arch Medical Group. Used with permission.
• RN-to-patient ratios that allow one-on-one care as needed during the Campath infusion
• Emergency medications, equipment, and procedures that are available and immediately accessible
• Physician proximity and availability during the Campath infusion.

If the care setting cannot meet these priority needs, patient safety may be compromised. This may be the case in underserved healthcare areas. Patients then must be redirected to a setting where these essential needs are more easily met.

Patient assessment is the next critical step prior to initiating Campath therapy. Key elements essential in this assessment are shown in Figure 1. The main components of the assessment are the risk factors for infection, including age, prior therapy, and prior history of infection. Concomitant medical problems and baseline laboratory values guide treatment modifications, such as prehydration and interventions for infusion-related events.

A past history of allergies may necessitate changes to the anti-infective regimen. For example, patients who are allergic to sulfa drugs require alternate protozoal prophylaxis with dapsone. A high baseline white blood count suggests a need for allopurinol to prevent hyperuricemia if rapid tumor lysis occurs.

**Patient Education**

Patient education prior to initiating treatment with Campath is crucial. Inadequate patient and caregiver education for Campath treatment can lead to frustration, poor compliance, and potential crisis. Patients and caregivers must understand their role in this therapy and have a strategy to meet their responsibilities (Shelton, 2000). Most of the patients’ and caregivers’ responsibilities hinge on communication and treatment plan adherence. The rigorous treatment schedule and anti-infective regimens dictate the need for adherence, and the risk of severe infection underlies the importance of communication. The development and design of patient-education materials must take into account patients’ abilities to manage their own treatment plans (Hays & McCartney, 1998). Patient-education tools are available from Berlex Laboratories, Campath’s distributor, and can be obtained by calling 800-473-5832. These tools include the following:

- Campath drug information, including potential short- and long-term side effects and goals of treatment
- A treatment regimen schedule and possible alterations
- An anti-infective regimen including drug name(s), dose(s), and schedules
- Healthcare team contact information, including spaces for names, phone numbers, and after-hours access
- A patient diary with a guide to record symptoms, supportive medications taken, anti-infective regimen adherence, and other notes
- Outside support and information resources (e.g., Leukemia Society of America, American Cancer Society)
- A schedule or calendar to mark physician visits or treatment appointments

**Treatment**

Recent attention has focused on the need to have procedures targeted toward the prevention of chemotherapy errors (Schulmeister, 1997). Orders preprinted by each clinic for Campath administration standardize a complex treatment plan for ease of implementation and reduction in the potential for errors. They also facilitate nursing care by making the treatment regimen and side effect management routine. The format of the standardized order set is not as important as the content. Figure 2 is a sample order set used in one group practice setting. Standing orders are not intended to manage individual patient nuances. Instead, they are to be used as basic guidelines for care and altered to meet individual patient needs.

Documentation of patient care and response to Campath is critical to the success of therapy. Apart from being a required part of care, documentation illustrates trends in patients’ responses and side effects and enhances the individualization of the care plan. The data and trends experienced by patients may be used to improve methods and patient outcomes. Documentation is especially crucial during the initial, widespread use of any new agent.

Documentation of Campath treatment mirrors the standing orders. The format is flexible; however, a flow sheet design simplifies Campath treatment documentation and gives an overall view of the treatment course (see Figure 3). Documentation tools must fit institutional needs and requirements. Essential components to capture with these tools include patient compliance with their anti-infective regimen, laboratory values (especially absolute neutrophil counts and platelet counts if performed on treatment day), baseline symptoms, vital signs, hydration, premedications, Campath infusion, and any patient reactions with subsequent interventions.

Elements of tools used for preassessment, patient education, and treatment were gleaned from a literature review of clinical experience with Campath in the research setting. Currently, this is the best evidence on which to base care decisions. Availability of Campath for general use will no doubt lead to new experiences and potential improvements in care standards. Mooney (2001) asserted “nurses need to perfect their ability to evaluate clinical data and consistently use the best available evidence to guide clinical decisions and recommendations” (p. 17). Ambulatory oncology nurses are in a key position to affect patient outcomes for treatment with Campath and other emerging therapies.

**Summary**

The challenges of ambulatory oncology warn to proceed with caution when accepting the responsibility of new, complex treatments such as MoAb therapy. Campath in patients with CLL is one of the most complex, resource-straining therapies available. Achievement of durable responses in heavily pretreated patients is promising (Keating, 1999). However, the regimen is grueling, toxicity can be severe, and often patients are compromised prior to starting therapy.

Nurses have the opportunity to enhance the quality of care that patients receive through appropriate pretreatment assessment of the facility and patients, comprehensive patient education, and development of standardized orders and documentation tools. Nurses can collect data to make necessary changes and improve patient outcomes. The recommendations for nursing care in this article are preliminary and based on limited available information. Updated recommendations are awaited pending widespread use and experience with Campath.

**Author Contact:** Karen Seeley, RN, BSN, OCN®, can be reached at seeklm@stlou.smhs.com

**References**


Rapid Recap

Nursing Care of Patients Receiving Campath®

- Campath® (alemtuzumab, Berlex Laboratories, Richmond, CA) is an approved treatment for refractory chronic lymphocytic leukemia.
- Campath has a high incidence of infusion-related toxicity, including severe rigors and hypersensitivity reactions.
- Campath causes profound T cell suppression that leaves patients vulnerable to opportunistic infection.
- Pretreatment assessment of patients and treatment facilities is essential to minimize complications.
- Standardized order sets and detailed patient-education tools are essential to simplify the treatment regimen and ensure compliance.
- Evaluation of patient outcomes based on data from widespread use of Campath will direct future nursing interventions for these patients.