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 not responded to fludarabine therapy and who have not responded to fludarabine therapy (Flynn and Byrd, 2000). 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. Pre-medication 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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Monoclonal antibodies are focused therapies with unique infusion-related complications. Campath® (alemtuzumab, Berlex Laboratories, Richmond, CA) is indicated for the treatment of refractory chronic lymphocytic leukemia and has a complicated administration schedule, severe infusion-related toxicity, and profound immunosuppressive capability. Ambulatory cancer care is challenging simply because of the complex nature of the disease. Management of complicated therapies, such as Campath, stretches resources and requires a coordinated effort by the healthcare team for successful patient outcomes.