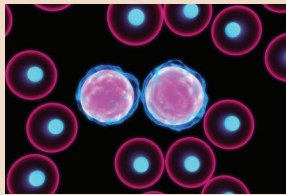


Managing Infusion-Related Reactions for Patients With Chronic Lymphocytic Leukemia Receiving Obinutuzumab

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Background: In patients with previously untreated chronic lymphocytic leukemia (CLL) and comorbidities, treatment with the glycoengineered, type II anti-CD20 monoclonal antibody obinutuzumab (Gazyva®) (GA101) plus chlorambucil (Leukeran®) was associated with superior outcomes to rituximab (Rituxan®) plus chlorambucil, with a similar safety profile. However, a higher occurrence of infusion-related reactions (IRRs) was reported with obinutuzumab. These reactions typically require additional management.

Objectives: The focus of this article is to provide oncology nurses and physicians with advice for obinutuzumab IRR management based on clinical trial data and nursing experience.

Methods: The authors reviewed the published management strategies for IRRs with obinutuzumab that were identified during the phase III CLL11 trial and an expanded access phase IIb study (ML28979). Practical advice for obinutuzumab IRR management was developed based on available clinical trial information and nursing experience.

Findings: IRRs with obinutuzumab are generally manageable. Most IRRs (all grades), and all grade 3–4 IRRs, occurred during the first infusion. Therefore, IRR management could be improved substantially with extra vigilance at this early stage.

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Treatment regimens containing the anti-CD20 monoclonal antibody rituximab (Rituxan®) have improved clinical outcomes in chronic lymphocytic leukemia (CLL) versus chemotherapy alone (Byrd et al., 2005; Foà et al., 2014; Goede et al., 2014; Hallek et al., 2010; Hillmen et al., 2014; Tam et al., 2008). Consequently, rituximab plus chlorambucil (Leukeran®) (R-C1b) is a current standard-of-care regimen for treatment-naïve, comorbid CLL (Hagemeister, 2010; Keating, 2010). However, CLL remains incurable using standard approaches (Rioufol & Salles, 2014); therefore, new therapies are needed to prolong CLL remission.

Obinutuzumab (Gazyva®) (GA101) is a novel, humanized, anti-CD20 monoclonal antibody (Abraham & Stegner, 2014) approved by the U.S. Food and Drug Administration in November 2013 for use with C1b regimens in patients with treatment-naïve CLL (Lee et al., 2014). The glycoengineered, type II antibody obinutuzumab enhances induction of antibody-dependent, cell-mediated cytotoxicity and direct cell death when compared to the type I antibody rituximab (Glennie, French, Cragg, & Taylor, 2007; Morschhauser et al., 2009, 2010; Mössner et al., 2010; Niederfellner et al., 2011). Obinutuzumab plus chlorambucil (G-C1b) has increased