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## A case report of successful alemtuzumab treatment of a B-CLL patient suffering from renal failure

F. Haslbauer

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Dear Editor,

A 72-year-old man was diagnosed with Rai stage II chronic lymphocytic leukemia (CLL) in January 2002 by another hospital. After an initial observation period, the patient's CLL progressed in January 2004, with lymphocyte counts increasing above  $100 \times 10^9$  per liter, accompanied by reduced platelet counts. Although no enlarged lymph nodes were detected, the presence of borderline splenomegaly was noted. The patient underwent physical examination, bone marrow biopsy, and a computed tomography scan. Further cytogenetic and immunophenotypic studies showed the presence of 13q deletion, low CD38 expression, and a low-risk ZAP 70 constellation, indicative of a favorable prognosis. In view of the presence of moderately elevated serum creatinine levels of unknown etiology, first-line single-agent chemotherapy with reduced-dose fludarabine was administered. Serum creatinine levels increased after two cycles and, as the patient's lymphocyte count responded well, chemotherapy was stopped in February 2004. The patient's renal function, as indicated by his serum creatinine levels, did not deteriorate further from February 2004 to the end of December 2004. However, at the beginning of 2005, his renal function progressively deteriorated and he developed renal failure in March 2005, at which time a Cimino shunt was established and hemodialysis was initiated.

In September 2005, the patient was transferred to our hospital for continuation of hemodialysis and clinical

oncology follow-up. He presented with a lymphocyte count of  $59 \times 10^9$  per liter. Repeated chest X-ray and abdominal ultrasound showed no significant lymph nodes or splenomegaly; constant monitoring for cytomegalovirus (CMV) infection did not reveal signs of reactivation and the patient's lymphocyte count increased slowly until it reached  $172 \times 10^9$  per liter in February 2007.

Further treatment with cytostatic chemotherapy was ruled out because of the patient's renal failure and because he was undergoing chronic hemodialysis. We decided to treat the patient with the humanized anti-CD52 monoclonal antibody alemtuzumab (MabCampath<sup>®</sup>, Bayer Schering Pharma AG, Berlin, Germany) via subcutaneous (SC) administration.

Dose escalation of alemtuzumab was carried out over the first 6 days: 10 mg on day 1, 20 mg on day 3, and 30 mg on day 6. Thereafter, alemtuzumab was administered at 30 mg on days 8, 10, 13, and 15. All SC injections of alemtuzumab were administered after hemodialysis. Alemtuzumab therapy was accompanied by the usual recommended premedication and anti-infective prophylaxis [1] consisting of sulfamethoxazole 400 mg–trimethoprim 80 mg and famciclovir 250 mg administered once daily after each hemodialysis procedure (Monday, Wednesday, Friday). Allopurinol 100 mg once daily was also administered after each hemodialysis procedure for prevention of hyperuricemia.

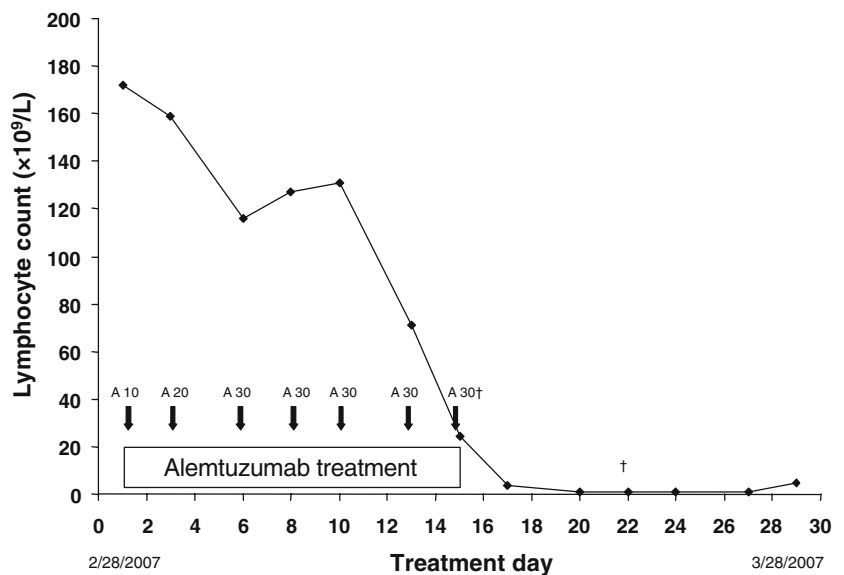
The effects of alemtuzumab therapy on the patient's lymphocyte count from February 28, 2007 (day 1) to March 28, 2007 (day 29) are shown in Fig. 1. During posttreatment follow-up, the patient's lymphocyte counts increased steadily from  $2.9 \times 10^9$  per liter on April 2, 2007 to  $7.5 \times 10^9$  per liter on November 5, 2007 and  $7.4 \times 10^9$  per liter on February 18, 2008. The patient's platelet count increased from  $138 \times 10^9$  per liter on February 28, 2007 to  $152 \times 10^9$

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Bayer Schering Pharma AG

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**Fig. 1** Alemtuzumab administration schedule and lymphocyte counts



per liter on April 2, 2007 and his hemoglobin level also increased from 10.9 to 11.9 g/dl from February 26 to March 28, 2007, indicative of a partial response to alemtuzumab therapy according to the National Cancer Institute criteria and a slowly progressive disease after 6 months of follow-up. Erythropoietin was administered throughout the period of hemodialysis at doses typically used in patients with renal insufficiency. No CMV reactivation was detected and the results of the patient's X-ray and ultrasound examinations remained normal. A bone marrow biopsy conducted on July 6, 2007 showed a remaining marrow infiltration of 45%. No adverse events (AEs) or toxicities were reported.

In this patient with CLL and renal failure undergoing chronic hemodialysis, second-line treatment with alemtuzumab produced a very rapid and durable hematologic response. SC injection of alemtuzumab has been shown to reduce the incidence of AEs related to intravenous administration in a phase II trial in previously untreated symptomatic patients with B-CLL [1, 2] and similar tolerability findings have also been noted in other studies that have assessed SC administration of alemtuzumab in both relapsed–refractory and untreated CLL patients [3–5]. However, this case provides the first report of the safety and efficacy of alemtuzumab in a patient with renal insufficiency. No major AEs, infections, or CMV reactivation were observed, and the patient (now 77 years old) remains well, with an excellent quality of life. Alemtuzumab will again

be the treatment of choice in the event of disease progression.

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