

Long-term follow-up for A041202

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Woyach JA, Perez Burbano G, Ruppert AS, Miller C, Heerema NA, Zhao W, Wall A, Ding W, Bartlett NL, Brander DM, Barr PM, Rogers KA, Parikh SA, Stephens DM, Brown JR, Lozanski G, Blachly J, Nattam S, Larson RA, Erba H, Litzow M, Luger S, Owen C, Kuzma C, Abramson JS, Little RF, Dinner S, Stone RM, Uy G, Stock W, Mandrekar SJ, Byrd JC. Follow-up from the A041202 study shows continued efficacy of ibrutinib regimens for older adults with CLL. *Blood*. 2024;143(16):1616-1627.

- Your patient is a 72-year-old man with chronic lymphocytic leukemia (CLL). Based on the long-term outcome data from the Alliance for Clinical Trials in Oncology study (A041202) by Woyach and colleagues, which of the following statements about ibrutinib (I) and ibrutinib plus rituximab (IR) vs bendamustine plus rituximab (BR) in CLL treatment is correct?**
 - 48-month progression-free survival (PFS) estimates were 47% for the BR arm, 76% for the I arm, and 76% for the IR arm
 - Overall survival (OS) was statistically significantly better for patients taking I or IR compared with BR
 - The benefit of I or IR varied considerably across subgroups of patients defined by *TP53* abnormalities, del(11q), complex karyotype, and immunoglobulin heavy chain variable region gene (IGHV)
 - There were significant interaction effects between the treatment arm and del(11q)
- Based on the long-term outcome data from the A041202 study by Woyach and colleagues, which of the following statements about safety and toxicity outcomes for I and IR vs BR in CLL treatment is correct?**
 - Atrial fibrillation (AF) and hypertension are most likely to occur soon after ibrutinib initiation, with stable incidence thereafter
 - Rates of hypertension were similar in patients treated with BR and those treated with ibrutinib
 - AF occurred in 11 patients on BR (3%) and in 67 patients on I (18%)
 - Discontinuation because of adverse events (AEs) was higher in the BR arm than in the I and IR arms throughout the study
- Based on the long-term outcome data from the A041202 study by Woyach and colleagues, which of the following statements about clinical implications of efficacy and safety outcomes for I and IR vs BR in CLL treatment is correct?**
 - The study shows that I is ineffective in high-risk subgroups of patients with CLL
 - Within the I arm, PFS was inferior for patients with abnormalities in *TP53*, the highest-risk feature in CLL
 - Most patients do well over many years on frontline I, but cardiac toxicities warrant consideration, especially in this older population
 - The study does not support continued use of I as a standard of care for frontline CLL therapy