Body Weight Gain Associated With Alectinib in Patients With ALK+ Non–Small Cell Lung Cancer: Pooled Analysis of Individual Patient Data From Four Prospective Clinical Trials

Abstract

Purpose

Weight gain is a known adverse event (AE) of alectinib. This study evaluates the progression of actual weight gain over time and explores its association with baseline characteristics.

Methods

A pooled analysis of individual patient data from four clinical trials (ALEX, J-ALEX, ALUR, and ML29453) was conducted. Actual weight gain was calculated as the percent change from baseline. A linear mixed model estimated weight change over time and associations between clinical characteristics and weight change.

Results

Follow-up weights were available for three trials (J-ALEX, ALUR, and ML29453) and missing for ALEX. In total, 2,622 weights were recorded in the first year (N = 302). At baseline, 13.6% of the Japanese population were underweight and 5.0% in the Western population. Actual weight gain of any grade was substantially higher than reported AE rates (49% *v* 5%), with 18% experiencing ≥10% weight gain (from median 55.6 kg to 64.1 kg). Time on alectinib was positively associated with weight change (β = .37; 95% CI, 0.24 to 0.51; *P* < .001), corresponding to an average increase of 4.4% over 1 year. Baseline BMI was not associated with weight change in J-ALEX (β = –.090 [95% CI, –0.19 to 0.012]; *P* = .092) and ALUR/ML29453 (β = –.016 [95% CI, –0.077 to 0.044]; *P* = .59). Baseline albumin was positively associated with weight change in ALUR/ML29453 (β = .084 [95% CI, 0.027 to 0.14]; *P* = .0045), although not considered a clinically meaningful predictor.

Conclusion

Weight gain is under-reported as AE in trials. Actual weights showed ≥10% weight gain in 18% of patients. Clinicians should be aware of this AE, emphasizing the importance of timely identification and monitoring weight. Identifying predictors for weight gain remains challenging.