1131 Performance of a novel 8-color flow cytometry panel in the detection of minimal residual disease assessment of chronic lymphocytic leukemia

Abstract

Background:The status of minimal residual disease (MRD) has been established as an important prognostic indicator in chronic lymphocytic leukemia (CLL).

Methods: Owing to the requirements of high accuracy, reproducibility and comparability of MRD, this study investigated the performance of a flow cytometric approach (CD45-ROR1 panel) in the MRD detection of CLL patients, with European Research Initiative on CLL (ERIC) 8-color panel as the “gold standard”.

Results: The sensitivity, specificity and concordance rate of CD45-ROR1 panel in the MRD assessment of CLL were 100% (87/87), 88.5% (23/26) and 97.3% (110/113), respectively. Two of the 3 non-consistent samples were further verified by the next-generation sequencing. In addition, the MRD results obtained from the CD45-ROR1 panel were positively associated with ERIC 8-color results for MRD assessment ($R=0.98$, $p<0.0001$). MRD detection at low levels (≤1.0%) demonstrated a smaller difference between the two methods (bias, -0.11; 95% CI, -0.90-0.68) as compared with that at high levels (0.1%). For the reproducibility assessment, the bias was smaller at three datapoints in the CD45-ROR1 panel as compared with that of ERIC 8-color panel. Moreover, MRD level detected using the CD45-ROR1 panel for the same samples between different laboratories showed a strong statistical correlation ($R=0.99$, $p<0.0001$) with a trivial inter-laboratory variation (bias, 0.135; 95% CI, -0.439-0.709). Interesingly, the MRD level detected in the lymph nodes samples were significantly higher than that of the peripheral blood and bone marrow samples ($p=0.029$).

Conclusions: Collectively, this study demonstrates that the CD45-ROR1 panel is a reliable method for the MRD assessment of CLL, with high sensitivity, reproducibility, and reliability.