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LETTER

Plasma Long Non-Coding RNA RP11-438N5.3 Level for Non-Small Cell Lung Cancer Diagnosis [Letter]

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Dear editor

Chen et al[1] published an article entitled "Plasma Long Non-Coding RNA RP11-438N5.3 as a Novel Biomarker for Non-Small Cell Lung Cancer" in the *Cancer Management and Research* journal. To evaluate the diagnostic efficiency of Plasma level of RP11-438N5.3 for non-small-cell lung cancer (NCLC), the investigators enrolled 69 NCLC patients and 69 healthy controls in this study. Plasma level of RP11-438N5.3 was determined using quantitative reverse transcription PCR (qRT-PCR), and receiver operating characteristic (ROC) curve analysis was assessed to determine the diagnostic performance of Plasma level of RP11-438N5.3 level in NCLC. They found that Plasma level of RP11-438N5.3 level was significantly lower in NCLC patients than healthy controls and the area under ROC curve (AUC) is 0.814. Therefore, they concluded that the Plasma level of RP11-438N5.3 was a novel diagnostic biomarker for NCLC.

The work performed by Chen et al is novel and interesting for finding a novel diagnostic non-invasive biomarker for NCLC. However, we would like to point out some limitations of this study. This study was neither pre-designed inclusion nor exclusion criteria for enrolling study cohort consecutively, and controls of the study were 69 healthy controls without NCLC. The design of diagnostic tests in this study is not a "one-gate" design study (The NCLC patients and controls are from two completely Irrelevant populations. The number of NCLC patients is crucial, if the proportion of NCLC patients is too high, there will be overestimated sensitivity. Whereas the proportion of controls is high, there will be an inflated estimate of sensitivity.[2]) in this study. Therefore, the diagnostic capability of the design of this study is deeply affected by the Irrelevant healthy controls.[3,4] It seems that the appropriate controls (Including benign bowel disease and healthy controls) are crucial for evaluating the diagnostic accuracy. There are any signs, symptoms and risk factors related to NCLC for healthy controls, and there is not necessary to test Plasma level of RP11-438N5.3 to distinguish between healthy controls and NCLC patients. This study should be using "one-gate design" (The NCLC patients and healthy controls are from the relevant population. The proportion of NCLC patients and controls is fixed and constant. Therefore, the sensitivity and specificity of the diagnostic tests will be constant, as long as the NCLC patients and controls come from the one population.[2]) for better to using both pre-specified inclusion and

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exclusion criteria for consecutively enrolling. In such a case, there are clinical presentations of NCLC for the participants of controls, and all samples of the entire cohort (come from a single population) whose Plasma level of RP11-438N5.3 should be tested.

In conclusion, the study seems to provide Plasma level of RP11-438N5.3 as a novel diagnostic biomarker for NCLC. However, due to the weakness of the design, they need rigorously evaluate the diagnostic values of owing to for NCLC using a further well-designed study. And we know very well that The different proportions of patients and controls will be different diagnostic efficiencies.[4] As far as we know, the number of controls includes healthy people and benign diseases, and the number is higher than cancer patients.

Disclosure

The authors report no conflicts of interest in this communication.

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