To the Editor:

Recently, Yoshinaga et al reported a validation study on the prediction of coronary artery disease (CAD) by an automated quantitative program for myocardial perfusion imaging. They used several indicators of single-emission computed tomography (SPECT) as a screening tool. Agreement was determined by the Bland-Altman method and \( \kappa \) statistics, and receiver-operating characteristic (ROC) curve analysis was applied to determine the optimal cut-off value for summed difference scores from \(^{201}\)Thallium SPECT myocardial perfusion images.

In their ROC curve analysis, they used coronary angiography (CAG) as the gold standard. I know the difficulty in obtaining a satisfactory number of samples, but only 7 patients out of 50 undergoing CAG examination is a serious problem for statistical validation. Hanley and McNeil presented appropriate numbers of samples in several different statistical models for ROC curve analysis, and Obuchowski and McClish reported the mathematical basis of adequate methods for sample size determination to keep the diagnostic accuracy of ROC curve analysis.

Furthermore, Obuchowski et al summarized a list of sample sizes (number of control patients and number of diseased patients) needed for an exploratory retrospective study, which could be applied to the data presented by Yoshinaga et al. Obuchowski et al listed several stratifications of the ratio between the number of control patients and the number of diseased patients in addition to the conjectured accuracy of the screening tool. Obuchowski et al mention in the footnote of their Table 4 that at least 10 diseased patients and 10 control patients are required to keep statistical validation of the ROC curve analysis. When the information in Table 4 and Figure 3 presented by Yoshinaga et al is overviewed, their results cannot be handled with confidence.

Although Yoshinaga et al comment in their study limitations, the statistical test to determine the threshold for the summed difference scores from \(^{201}\)Thallium is indispensable by increasing the sample size. The sensitivity analysis and \( \kappa \) statistics presented in Table 4 clearly lack validation of the study. They keep a randomly selected 50 patients from 196 with known or suspected CAD, and I recommend continuous gathering of CAG cases to make a validated analysis.

Disclosures

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References


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