Cardiac disease is the second leading cause of death in Japan today, and the incidence of ischemic disease in Japan is increasing with the advent of an aging society and the westernization of diet. Recent guidelines recommend that examinations such as exercise ECG and drug/exercise myocardial scintigraphy be performed before coronary angiography.

Multiinction CardioGram (MCG) performs a frequency analysis of several minutes of resting electrocardiogram information using six calculation formulas (Auto Power Spectrum, Phase Angle Shift, Impulse Response, Cross Correlation, Coherence Function, and Transfer Function). It is a system that can detect death and disease centered on myocardial ischemia by comparing with a database of frequency patterns caused by heart disease. In the United States, MCG analysis has already been approved by the FDA in 2003 for ischemic heart disease, and in January 2010, the CPT code (medical report Elll billing code) was obtained.

Multifunction CardioGram Evaluation in Diagnosis of Functional coronary Ischemia sTudy (MED FIT) has been evaluated by Fractional Flow Reserve (FFR) since August 2013 in 100 patients scheduled for coronary angiography at Kyoto University Hospital. This is a single-center, prospective study that investigated the diagnostic ability of the MCG severity score for functional myocardial ischemia. As a result of this study, the diagnostic ability of the MCG score was found not only for functional ischemia (FFR <= 0.80), but also for significant stenosis (% diameter stenosis >= 50%) on Quantitative Coronary Angiography (QCA). We have already reported that is not sufficient.

In this follow-up study we used the severity score as a follow-up analysis, and compared the results of MCG session analysis and coronary angiography to interpret the suspicion of ischemic heart disease based on the information provided in the MCG report. Therefore, we investigated the usefulness of MCG as a screening tool for coronary arteriosclerosis.
This study was conducted with the approval of the ethics committee of the same facility.

In the present study, session analysis was also performed, taking into account the positive physiological/pathophysiological condition data and the local/global ischemia classification in the reference information attached to the MCG analysis report (Fig. 1). Session analysis was positive only when the following two conditions were met, even among those with a severity score less than the set value. At least 2 out of 5 modeling items were positive. Sessions in which both local and global 2 ischemia outcome items were false were not included.

In MED FIT, FFR was evaluated using a pressure wire when a coronary artery lesion with a stenosis of 30% or more was observed in a blood vessel with a diameter of 2 mm or less by coronary angiography. In the same sub-analysis, the presence of coronary artery lesions with an inner diameter stenosis of 30% or more on coronary angiography was defined as coronary arteriosclerosis, and the primary endpoint was the sensitivity and specificity of MCG session analysis for coronary arteriosclerosis.

Results

Nine of the 100 patients had poor quality ECG information during all 20 min resting sessions and were excluded from the analysis. The median age of the subjects was 71.2 years old, and 48.3% were male. In addition, more than 70% of patients had hypertension and dyslipidemia, and more than 20% had diabetes and smoking history. Atrial fibrillation at the time of measurement was observed in 6.6% (Table 1).

Of the 91 patients, 64 (70.3%) had coronary arteriosclerosis on coronary angiography. There was almost no significant difference in patient background between the presence or absence of coronary arteriosclerosis, but atrial fibrillation was observed only in the group without coronary arteriosclerosis (0 [0.0%] vs. 6 [22.2%], P< 0.001). He found no significant difference in the MCG severity score (3.2 versus 2.3, P = 0.16).

Table 2 shows the sensitivity and specificity of the MCG Session analysis. Accuracy rate was highest at 2.0 cutoff value, 81.3%, and sensitivity/specificity was 90.6%/59.3%.

Conclusions

There are various tests for screening coronary artery disease, but the sensitivity and specificity of conventional physiological function tests are not sufficient. / 73%89. MCG is non-invasive, unlike other ischemia diagnostic tests, because it analyzes electrocardiogram information at rest. Furthermore, previous reports have reported that the sensitivity/specificity of significant stenosis (visual observation) in coronary angiography with a severity score of 4.0 as a cut-off value is as high as 89.1-90.9%/81.1-88.0%.
Because of its non-invasiveness and high diagnostic performance, it was approved by the FDA in the United States in 2003, and received a CPT code in January 2010 to determine whether it is appropriate as a cut-off point for sclerosis. However, in MED-FIT, the sensitivity/specificity of the severity score with a cut-off value of 4.0 for functional ischemia using FFR was 32%/67%, the ROC curve was AUC 0.51, and the QCA-enhanced contrast was improved. Sensitivity/specificity was 37%/72% and ROC curve was AUC 0.58 even for the above significant stenosis.

In this sub-analysis, coronary atherosclerosis was defined as having a coronary artery lesion with 30% or more inner diameter stenosis on day vision, and the usefulness of MCG as a screening tool for early detection of coronary artery disease was investigated. Moreover, not only the severity score but also the positive items in the reference information attached to the MCG analysis report and the local/wide area results of ischemia were taken into consideration for interpretation. Usually, when the seventy score is less than 2.0 points, the five items of reference information, ventricular hypertrophy, global asynchrony, increased myocardial compliance, decreased myocardial compliance, and dead muscle remodeling are almost 1 day old. However, even if the severity score is less than 2.0 points, if two or more of the above items are positive, the possibility of ischemic change must be considered. On the other hand, if there is a session in which both local and extensive items were false, it must be judged as negative for MCG session analysis because it is non-vascular (Fig. 1). As a result, the severity score by session analysis with MCG analysis report information taken into consideration showed high sensitivity and specificity of 90.6%/ 59.3% when the cut-off value was 2.0, demonstrating its usefulness as a screening test. (Table 2). Although decipherment is somewhat complicated,By performing MCG session analysis based on MCG analysis report information, it is possible to detect coronary arteriosclerosis with high sensitivity.

[Conflict of interest Disclosure: This research was commissioned by Toray Medical Co., Ltd., a distributor of the MCG product.]