PROSPECTIVE RANDOMIZED TRIAL ON RADIATION DOSE ESTIMATES OF CT ANGIOGRAPHY IN PATIENTS SCANNED WITH A HIGH-PITCH-FIRST SCAN STRATEGY - THE PROTECTION IV STUDY

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Background: Concerns have been raised about the radiation exposure during coronary CT angiographies (CCTAs). For a prospectively ECG-triggered high-pitch scan protocol very low and even sub-millisievert radiation doses have been reported for CCTA, but it is unclear, whether image quality is maintained when compared to conventional CCTA. The multi-center, prospective, randomized PROTECTION IV study investigates the impact of the high-pitch CCTA protocol on image quality and radiation dose.

Methods: 303 patients with suspected coronary artery disease and low and stable heart rate were randomized to either a high-pitch-first or a conventional-first CCTA strategy. In the conventional-first CCTA arm, ECG-triggered axial or ECG-gated low-pitch helical CT data acquisitions were used. If image quality was deemed insufficient with the first CCTA scan, a second scan was performed. The primary study endpoint was to show the diagnostic non-inferiority of the high-pitch scan protocol, which was assessed by a 4-point image quality grading score (1: nondiagnostic to 4: excellent image quality; predefined non-inferiority margin of 0.25 score points). Total radiation dose, the need for a second CCTA scan as well as the rate of downstream testing during 30-day follow-up were assessed as secondary endpoints.

Results: 150 and 153 patients were randomized to high-pitch-first and conventional-first CCTA groups, respectively. The mean heart rate and BMI were 57.6 ±4.0 bpm and 26.5 ±3.7 kg/m², respectively. A second CCTA scan was performed in 14.0% and 9.2% of patients in the high-pitch-first and conventional-first groups, respectively (P=0.187). The resulting total CCTA dose was 2.0 ± 2.4 mSv and 4.6 ± 4.8 mSv in the high-pitch-first and conventional-first groups, respectively (P<0.0001). In 74 (49.3%) patients of the high-pitch-first group the total CCTA dose was below 1 mSv.

Conclusions: Compared with a conventional-first CCTA scan strategy, the use of an ECG-triggered high-pitch-first scan strategy results in 58% reduction in total CCTA radiation dose with a large proportion of patients scanned in the submillisievert range. The final results including the image quality score will be presented.