無症状の糖尿病患者に対するCCTAは支持されない（Abstract 20773）

FACTOR-64：糖尿病患者の冠動脈疾患検出目的でのCT血管造影を用いたルーチンのスクリーニングは不要である

FACTOR-64: Routine screening of patients with diabetes for coronary artery disease with CT angiography not necessary

冠動脈コンピュータ断層血管造影（CCTA）を用いた糖尿病患者のスクリーニングの結果、少数において血行再建術が必要となり、スタチン使用が増加し、血圧およびLDL-Cが低下したが、4年後の心血管イベントは有意に低下させなかった。トライアルは*JAMA*に掲載され、2014年American Heart Association年次集会における発表と同時に公表された。研究者らは、少なくとも罹病期間が3～5年の1型または2型糖尿病で冠動脈疾患症状のない患者900人をCCTAを用いたスクリーニング（452人）または標準的な国内ガイドラインに基づいた糖尿病管理（448人）を行う群にランダムに割り付けた。標準的または強化療法（脂質、血圧および血糖値の治療に対して）は、CCTA所見に基づき推奨値を決定された。平均追跡期間4年後に、一次アウトカムイベント率（死亡、非致死性MI、または入院を要する不安定狭心症の合計）はCCTAとコントロール群とで有意差がなかった（6.2% 対7.6%、p=0.38）。虚血性主要有害心イベントである二次複合エンドポイントもまた2群間で差がなかった（4.4%対3.8% 、p=0.68）。これらの結果はこれらの患者群におけるCCTAスクリーニングを支持しないものであった。

Full Text

Joseph B. Muhlestein, M.D., of the Intermountain Medical Center Heart Institute, Murray, Utah, and colleagues examined whether screening patients with diabetes deemed to be at high cardiac risk with coronary computed tomographic angiography (CCTA) would result in a significant long-term reduction in death, heart attack, or hospitalization for unstable angina. The study appears in *JAMA* and is being released to coincide with its presentation at the American Heart Association's Scientific Sessions 2014.

Diabetes mellitus is the most important coronary artery disease (CAD) risk factor; patients with diabetes often develop severe but asymptomatic CAD. The combination of aggressive, asymptomatic CAD has made it the most common cause of death in patients with diabetes. The development of cardiac imaging with high-resolution CCTA now provides the opportunity to evaluate the actual coronary anatomy noninvasively and ascertain the overall extent and severity of coronary atherosclerosis. However, whether routine CCTA screening in high-risk populations can effect changes in treatment (such as preemptive coronary revascularization or more aggressive medical therapy), leading to a reduction in cardiac events, remains unproven, according to background information in the article.

The FACTOR-64 trial randomly assigned 900 patients with types 1 or 2 diabetes of at least 3 to 5 years' duration and without symptoms of CAD to CAD screening with CCTA (n = 452) or to standard national guidelines-based optimal diabetic care (n = 448). Patients were recruited from 45 clinics and practices of a single health system (Intermountain Healthcare, Utah). Standard or aggressive therapy (for treating abnormal lipid, blood pressure and glucose levels) was recommended based on CCTA findings.

At an average follow-up time of 4 years, the primary outcome event rates (composite of all-cause death, nonfatal heart attack, or unstable angina requiring hospitalization) were not significantly different between the CCTA and the control groups (6.2 percent [28 events] vs. 7.6 percent [34 events], p=0.38). The incidence of the composite secondary end point of ischemic major adverse cardiac events (CAD death, nonfatal heart attack, or unstable angina) also did not differ between groups (4.4 percent [20 events] vs. 3.8 percent [17 events], p=0.68).

"Coronary computed tomographic angiography involves significant expense and radiation exposure, so that justification of routine screening requires demonstration of net benefit in an appropriately high-risk population," the authors write. "These findings do not support CCTA screening in this population."

"What are the take-home messages from this randomized trial," asks Raymond J. Gibbons, M.D., of the Mayo Clinic, Rochester, Minn., in an accompanying editorial.

"Although studies like this are often characterized as 'negative,' there are several important messages. As suggested by the authors, future randomized trials of cardiac imaging in asymptomatic patients with diabetes should be larger and focused on an enriched study population at higher risk. Such a strategy would certainly enhance the chances of success. A more important and more currently applicable message is that guideline-directed medical therapy for hypertension and hyperlipidemia is effective in asymptomatic patients with diabetes and should be implemented more consistently. The data in this study suggest that Intermountain Healthcare has set a new published standard for what is achievable in patients with diabetes with respect to blood pressure control and lipid-lowering therapy and that, when therapy is applied this effectively, patients with diabetes are no longer at high risk for major cardiovascular events."

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