CTAと機能的検査による転帰は同等である (Abstract 400-16)

PROMISE：冠動脈CT造影はハードエンドポイントを軽減させないがより良いケア計画を促進させる

PROMISE: CT angiography does not reduce hard clinical endpoints but promotes better care planning

心疾患症状を有する患者に機能的負荷試験や冠動脈CT検査を施行しても死亡や主要な心疾患の転帰の点では同等であるが、心疾患のない患者に対しさらに検査や処置を行う必要性を除外するにはCT検査の方が優れているようであるとの研究結果が第64回American College of Cardiology年次集会で発表され、*New England Journal of Medicine*に掲載された。PROMISEトライアルは、過去に冠動脈疾患の診断を受けたことはないが医師が心疾患を疑うような新たな症状を有する計10,003人の患者を対象とした。半数は冠動脈CT造影（CTA）検査を受ける群にランダムに割り付けられた。その他の患者は機能的検査（運動負荷心電図、負荷心エコー検査または負荷核医学検査のいずれか）を受けた。スタディの一次エンドポイントである死亡、心筋梗塞、重大な施術合併症または胸痛による入院の合計に関して群間差はなかった。しかし、被曝量や有意な心疾患を示さなかったその後の検査の施行率などのいくつかの二次エンドポイントにおいては、CTAの方が好ましい結果であった。

Full Text

Patients with symptoms of heart disease have similar outcomes in terms of death and major cardiac conditions regardless of whether they undergo a functional stress test or a computed tomographic scan, but the scan may be better at ruling out the need for subsequent tests and procedures in patients who are free of heart disease, according to research presented at the American College of Cardiology's 64th Annual Scientific Session in San Diego.

The PROMISE trial is the first-ever randomized controlled trial to compare clinical outcomes in patients receiving functional stress testing or computed tomographic angiography (CTA) to check for signs of cardiovascular disease. It also provides the first data to inform clinical guidelines on the use of these tests, according to the authors.

The study included a total of 10,003 patients who visited 193 health centers in the United States and Canada. Participants had no prior diagnosis of coronary artery disease but had new symptoms that made physicians suspect they might have heart disease. Nearly all had at least one cardiovascular risk factor such as high blood pressure, diabetes or a history of smoking.

Half were randomly selected to receive a heart CT scan. The rest received a functional test—either an exercise electrocardiogram, stress echocardiography or nuclear stress test. All of these tests have been in common use for a decade or more but functional tests and CTA have never before been compared head-to-head in terms of clinical outcomes.

The study showed no differences between patients receiving a CTA and those receiving functional heart tests in terms of the study's primary endpoint, a composite rate of death, heart attack, major procedural complications or hospitalization for chest pain. At least one of these outcomes occurred in roughly 3 percent of patients in both groups during more than two years of follow-up.

However, some secondary endpoints, including the level of radiation exposure and the rate of subsequent procedures that did not reveal significant heart disease, favored computed tomographic angiography.

Authors said these results are important because current clinical guidelines leave the selection of tests for patients reporting symptoms such as chest pain or shortness of breath largely up to physician and patient preference.

"Until this study, we have essentially been guessing on decisions about which initial test to use for this huge population of patients who need evaluation for cardiovascular symptoms," said Pamela Douglas, M.D., the Ursula Geller Professorship for Research in Cardiovascular Diseases at Duke University and the study's lead author. "Our study shows that the prognostic outcomes are excellent and are similar regardless of what type of test you use, but there are some indications that computed tomographic angiography might be the safer test with fewer catheterizations without obstructive disease and lower radiation exposure when compared to nuclear testing."

A key strength of the study is that it offers a reflection of current medical practice, rather than an idealized view.

"Unlike most trials where medical care is very tightly controlled, this study was designed to represent real world care," Douglas said. "The health centers that collected the data were responsible for interpreting the tests and doing appropriate patient follow-up."

The 3 percent rate of death, myocardial infarction, major procedural complications or hospitalization for chest pain seen in both groups was lower than expected, especially considering the fact that most study participants had two or more significant heart disease risk factors, were middle aged or older and symptomatic. The relative benefit of CTA compared to functional testing held steady across different patient subgroups as defined by age, gender, race and cardiovascular risk factors. Although there was a significantly lower rate of death and non-fatal MI after one year of follow-up in patients receiving a heart CT scan, for reasons that are unclear, this difference was not sustained in the second year, study authors said.

"The event rate in itself is intriguing, because no previous studies have closely tracked and adjudicated the rate of adverse events in this patient population," Douglas said. "These outcomes are so good given widespread use of medications like statins and aspirin. It does raise the question of whether we can identify a group of people who actually do not need to be tested."

After their initial non-invasive test, about 10 percent of study participants underwent at least one cardiac catheterization procedure. The rates of patients undergoing catheterization that failed to identify substantial narrowing were significantly higher in the patients receiving functional testing, at 4.3 percent, compared to 3.4 percent in the patients who had received a CT scan.

In addition, at three months patients receiving heart scans received significantly lower radiation exposure than patients who were given a nuclear stress test as their first diagnostic test.

Douglas said the bottom line for patients is that if the primary concern is avoiding serious adverse heart problems such as death, heart attack or hospitalization, heart CT scans and functional tests are both excellent options. For lower-priority concerns such as avoiding subsequent tests and procedures or avoiding radiation exposure, CTA appears to be a slightly better option.

Douglas said the team plans to further investigate outcomes for different subgroups of patients to determine whether different groups might benefit from different testing approaches.

The research team also analyzed the financial implications of the data in terms of medical costs and reimbursements, which will be presented separately.

The study was funded by the National Heart, Lung, and Blood Institute of the National Institutes of Health.

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