橈骨動脈からのアクセスにより血管系合併症が減少する

RIVAL：橈骨動脈からアクセスして冠動脈インターベンションを行うことにより成功率は維持される一方血管系合併症は減少する

RIVAL: Radial access for coronary interventions reduces vascular complications while maintaining angioplasty success rates

冠動脈造影および冠動脈インターベンションの際の橈骨動脈穿刺と大腿動脈穿刺を比較した最大規模のスタディにおいて、橈骨動脈からのアクセスにより血管系合併症が減少する一方成功率は維持されることが示されたとの研究結果が第60回American College of Cardiology学会で発表され、Lancetに掲載された。このRIVALスタディにおいて、7,021人の患者が橈骨動脈（3,507人）または大腿動脈（3,514人）からのアクセスにより施術を受ける群に無作為に割り付けられた。一次エンドポイント（30日間の死亡、心筋梗塞（MI）、脳卒中、またはCABG以外による重大な出血）発現に関してはそれぞれ3.7%と4.0%（p=0.50）で、両アプローチにおいて同様の結果であった。血管形成術成功率も両群間で同等であった(p=0.83)。しかし、主要な血管系合併症に関して調査すると、橈骨動脈群において1.4%であったのと比較し大腿動脈群においては3.7%であり、橈骨動脈群の方が成績は良好であった。ST上昇MI患者においても、一次エンドポイントおよび死亡率に関して橈骨動脈の方が結果は良好であった。橈骨動脈穿刺の施術数の多い施設において、大腿動脈穿刺よりも橈骨動脈穿刺の成績が良好であった。穿刺部位の重大な出血は全て大腿動脈穿刺部位において発生した。

Full Text

In the largest randomized trial to compare radial access and femoral access for coronary angiography and intervention, researchers found that radial access led to reduced rates of vascular complications while maintaining similar angioplasty success rates, according to research presented at the American College of Cardiology's 60th Annual Scientific Session (ACC.11).

The trial also found that radial access did not reduce the primary outcome measure of death, myocardial infarction, stroke, and non-CABG-related major bleeding compared to femoral access in the overall study population. However, radial access did lead to reductions in the primary outcome measure in patients who underwent the procedure at hospitals that conducted a high volume of radial procedures.

The RIVAL trial was designed to help determine the optimal access site for coronary angiography and intervention in patients with acute coronary syndromes. While prior data have shown that radial access results in fewer bleeding complications than femoral access, this information has only come from observational studies and small randomized trials. In addition, there has been concern that radial access could be associated with a greater angioplasty procedural failure rate.

Across the past two decades, femoral access has been used in approximately 95 percent of coronary angiography and interventional procedures in the United States. However, the data from the previous observational studies suggest that the radial artery is associated with a 50 percent to 60 percent reduction in the odds of major bleeding, which is strongly associated with a reduction in mortality.

Thus, the study researchers believed this alternate route may be an attractive option for interventional cardiologists.

"It is increasingly recognized that preventing bleeding complications may be just as important as preventing recurrent ischemic complications in patients with acute coronary syndromes," said Sanjit Jolly, M.D., M.Sc., assistant professor of medicine at McMaster University in Hamilton, Ontario, Canada. "Our hypothesis was that radial access would reduce access site bleeding with preserved angioplasty efficacy."

This international, multicenter study randomized 7,021 patients to receive either radial access (n = 3507) or femoral access (n = 3514).

The primary outcome measure was the incidence of death, heart attack, stroke, or non-CABG-related major bleeding at 30 days. Other outcome measures included angioplasty procedural success and major vascular access site complications at 48 hours and 30 days post-procedure.

The research team found that radial access and femoral access performed similarly with regard to the primary outcome measure, with 3.7 percent and 4.0 percent of patients, respectively, experiencing death, heart attack, stroke, or non-CABG-related major bleeding at 30 days (hazard ratio [HR] 0.92; 95 percent confidence interval [CI] 0.72 - 1.17; p = 0.50). Both groups also showed similar rates of angioplasty success, at 95.4 percent of patients in the radial group and 95.2 percent of patients in the femoral cohort (HR 1.01; 95 percent CI 0.95 - 1.07; p = 0.83).

Radial access performed better, however, when the team examined major vascular complications. Specifically, 1.4 percent of patients in the radial cohort developed this outcome, compared to 3.7 percent of patients in the femoral group (HR 0.37; 95 percent CI 0.27 - 0.52; p <0.001). Radial access also yielded better results in patients with ST-segment elevation heart attack for the primary outcome measure and for mortality. Furthermore, radial access had better outcomes than femoral access at institutions that performed a high volume of radial procedures (the converse was not seen at institutions performing many femoral access procedures). In addition, all access site major bleeds occurred at the femoral arterial access site.

"The results of the RIVAL trial show that both access sites are safe and effective," Jolly said. "The reduction in vascular access complications may be a reason for interventional cardiologists to use radial access. Furthermore, the effectiveness of the radial approach may improve with greater expertise and procedural volume."

The study was funded by Sanofi-Aventis, the Population Health Research Institute, and the Canadian Network and Center for Trials Internationally (funded through the Canadian Institutes of Health Research). Jolly disclosed that he received institutional research grants from Sanofi-Aventis, Bristol- Myers Squibb, and Medtronic. He also received consulting fees from Sanofi-Aventis, GlaxoSmithKline, and AstraZeneca.

The study was simultaneously published in The Lancet at the time of presentation.

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