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CORONARY

RADIAL ACCESS FOCUS

Radial Versus Femoral Access for Coronary Angiography/Intervention in Women With Acute Coronary Syndromes

Insights From the RIVAL Trial (Radial Vs femorAL access for coronary intervention)

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ABSTRACT

OBJECTIVES The purpose of this study was to determine the efficacy and safety of radial versus femoral access in women undergoing coronary angiography/intervention.

BACKGROUND The risk of bleeding and vascular access site complications are higher in women than in men.

METHODS In a pre-specified RIVAL (RadIal Vs femorAL access for coronary intervention) subgroup analysis, we compared outcomes in women (n = 1,861) and men (n = 5,160) randomized to radial versus femoral access.

RESULTS Overall, women were at higher risk of major vascular complications compared with men (4.7% vs. 1.7%; $p < 0.0001$). Major vascular complications were significantly reduced with radial access in women (3.1% vs. 6.1%; hazard ratio [HR]: 0.5; 95% confidence interval [CI]: 0.32 to 0.78; $p = 0.002$) and in men (0.7% vs. 2.8%; HR: 0.27; 95% CI: 0.17 to 0.45; $p < 0.0001$; interaction $p = 0.092$). Crossover rates were higher with radial compared with femoral access in women (11.1% vs. 1.9%; HR: 5.88; $p < 0.0001$) and men (6.3% vs. 1.9%; HR: 3.32; $p < 0.0001$; interaction $p = 0.054$). Percutaneous coronary intervention (PCI) success rates were similar irrespective of access site (women: HR: 1.05; $p = 0.471$; men: HR: 1.00; $p = 0.888$; interaction $p = 0.674$), with no differences in PCI complications. In multivariable analyses, female sex was an independent predictor of major vascular complications (HR: 2.39; 95% CI: 1.76 to 3.25; $p < 0.0001$). There were consistent findings for women and men, with no difference for the primary composite endpoint of death, myocardial infarction, stroke, and non-coronary artery bypass grafting bleeding (women: 3.9% vs. 5.0%; HR: 0.77; 95% CI: 0.50 to 1.19; men: 3.54% vs. 3.5%; HR: 1.00; 95% CI: 0.75 to −1.34; interaction $p = 0.325$).

CONCLUSIONS Women undergoing coronary angiography and PCI have a higher risk of vascular access site complications compared with men, and radial access is an effective method to reduce these complications. (J Am Coll Cardiol Intv 2015;8:505-12) © 2015 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

CABG = coronary artery bypass grafting

CI = confidence interval

GP = glycoprotein

HR = hazard ratio

NNT = number needed to treat

PCI = percutaneous coronary intervention

STEMI = ST-segment elevation myocardial infarction

Over the past 5 years, there has been an increase in the uptake of radial access for percutaneous coronary intervention (PCI) for both elective and emergency cases in Europe and North America (1–3). The RIVAL (RadIal Vs femorAL access for coronary intervention) trial randomized 7,021 patients with acute coronary syndrome to either radial or femoral access for coronary angiography and PCI and showed that, overall, there was no difference in the primary composite outcome of death, myocardial infarction (MI), stroke, or non-coronary artery bypass graft (CABG) bleeding, with a significant reduction in major vascular complications (4).

Observational data suggest that female sex is an independent risk factor for major bleeding and that the use of radial access for PCI likely reduces this risk (5,6). However, there are concerns that radial access may be technically more challenging in women due to smaller radial arteries and increased rates of radial artery spasm, potentially leading to lower procedural success rates. Most randomized trials comparing radial with femoral access have enrolled more men than women, making data regarding radial access specific to women very pertinent (7).

SEE PAGE 513

We sought to determine the efficacy and safety of radial versus femoral access in women and men in this pre-specified subgroup analysis.

METHODS

RIVAL was a randomized, parallel-group, multicenter trial. Patients with acute coronary syndromes, with or without ST-segment elevation, and planned for invasive therapy were included. Patients with cardiogenic shock, severe peripheral arterial disease precluding femoral approach, previous coronary bypass surgery with use of more than 1 internal mammary artery, and a negative Allen's test (absence of dual circulation of hand) were ineligible for inclusion. The study was approved by all appropriate national regulatory authorities and ethics committees of participating centers, and participants provided written informed consent prior to enrollment. The trial was coordinated by the Population Health Research Institute at McMaster University and Hamilton Health Sciences in Hamilton, Ontario, Canada. Details of RIVAL's study design are published elsewhere (4,8).

The primary efficacy outcome was a composite of death, MI, stroke, or non-CABG major bleeding at 30 days. Other outcomes included composite of death, MI, or stroke; components of primary outcome; major vascular complications; access site pain; crossover rates; PCI success and complication rates; procedure duration; contrast volumes used; and patient preference for next procedure.

Major vascular complications included retroperitoneal hematoma, pseudoaneurysm requiring ultrasound compression, thrombin injection or surgical repair, large hematomas requiring prolonged hospitalization, arteriovenous fistulae, limb ischemia or damage to adjacent nerve, and other surgical access site repair. RIVAL major bleeding was defined as bleeding that was fatal; resulted in transfusion of ≥2 U red blood cells; caused significant hypotension requiring inotropes; required surgical intervention; caused severe disabling sequelae; was intracranial or intraocular; or led to a drop in hemoglobin of at least 50 g/l. ACUITY (Acute Catheterization and Urgent Intervention strategy) non-CABG-related major bleeding was defined as RIVAL major bleeding, large hematomas, and pseudoaneurysms requiring intervention (4).

STATISTICAL ANALYSES. The final intention-to-treat analyses included all patients, irrespective of whether they crossed over to another access site or did not undergo PCI. A significance level of 0.05 with 2-sided test was used, and all analyses were performed using SAS version 9.2 (SAS Institute, Cary, North Carolina).

Women versus men was 1 of 6 pre-specified, pre-randomization subgroups. The efficacy and safety of radial versus femoral access for the primary and secondary outcomes in women versus men were assessed by comparison of survival curves (estimated with the Kaplan-Meier method) for the 2 approaches by log-rank statistic. The interaction p value was then calculated to estimate any significant differences between women and men. Centers were included as random effects in the COX model to account for any intercenter variability. Demographic, baseline therapy, clinical, investigatory, and procedural characteristics of the 2 comparison groups were compared using chi-square and Wilcoxon rank sum tests as appropriate.

A multivariable analysis using the Cox proportional hazard model was performed to determine whether women versus men was independently associated with increased risk of major vascular complications after adjusting for sex, age, body mass index, diabetes, arterial sheath size, use of a closure device, whether PCI was performed, glycoprotein (GP) IIb/IIIa inhibitor use, ST-segment elevation myocardial infarction