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Procedural Volume and Outcomes With Radial or Femoral Access for Coronary Angiography and Intervention

Sanjit S. Jolly, MD, MSc,* John Cairns, MD,† Salim Yusuf, MBBS, DPhil,* Kari Niemela, MD, PhD,‡ Philippe Gabriel Steg, MD,§ Matthew Worthley, MD,‖ Emile Ferrari, MD,¶ Warren J. Cantor, MD,# Anthony Fung, MD,† Nicholas Valettas, MD, MSc,* Michael Rokoss, MD,* Goran K. Olivecrona, MD, PhD,** Petr Widimsky, MD,†† Asim N. Cheema, MD, PhD,‡‡ Peggy Gao, MSc,* Shamir R. Mehta, MD, MSc,* for the RIVAL Investigators

Hamilton and Toronto, Ontario, and Vancouver, British Columbia, Canada; Tampere, Finland; Paris and Nice, France; Adelaide, Australia; Lund, Sweden; and Prague, Czech Republic

Objectives The study sought to evaluate the relationship between procedural volume and outcomes with radial and femoral approach.

Background RIVAL (RadIal Vs. femorAL) was a randomized trial of radial versus femoral access for coronary angiography/intervention (N = 7,021), which overall did not show a difference in primary outcome of death, myocardial infarction, stroke, or non–coronary artery bypass graft major bleeding.

Methods In pre-specified subgroup analyses, the hazard ratios for the primary outcome were compared among centers divided by tertiles and among individual operators. A multivariable Cox proportional hazards model was used to determine the independent effect of center and operator volumes after adjusting for other variables.

Results In high-volume radial centers, the primary outcome was reduced with radial versus femoral access (hazard ratio [HR]: 0.49; 95% confidence interval [CI]: 0.28 to 0.87) but not in intermediate- (HR: 1.23; 95% CI: 0.88 to 1.72) or low-volume centers (HR: 0.83; 95% CI: 0.52 to 1.31; interaction p = 0.021). High-volume centers enrolled a higher proportion of ST-segment elevation myocardial infarction (STEMI). After adjustment for STEMI, the benefit of radial access persisted at high-volume radial centers. There was no difference in the primary outcome between radial and femoral access by operator volume: high-volume operators (HR: 0.79; 95% CI: 0.48 to 1.28), intermediate (HR: 0.87; 95% CI: 0.60 to 1.27), and low (HR: 1.10; 95% CI: 0.74 to 1.65; interaction p = 0.536). However, in a multivariable model, overall center volume and radial center volume were independently associated with the primary outcome but not femoral center volume (overall percutaneous coronary intervention volume HR: 0.92, 95% CI: 0.88 to 0.96; radial volume HR: 0.88, 95% CI: 0.80 to 0.97; and femoral volume HR: 1.00, 95% CI: 0.94 to 1.07; p = 0.98).

Conclusions Procedural volume and expertise are important, particularly for radial percutaneous coronary intervention. (A Trial of Trans-radial Versus Trans-femoral Percutaneous Coronary Intervention [PCI] Access Site Approach in Patients With Unstable Angina or Myocardial Infarction Managed With an Invasive Strategy [RIVAL]; NCT01014273) (J Am Coll Cardiol 2014;63:954–63) © 2014 by the American College of Cardiology Foundation

From the *McMaster University and Population Health Research Institute, Hamilton Health Sciences, Hamilton, Ontario, Canada; †University of British Columbia, Vancouver, British Columbia, Canada; ‡Tampere University Hospital and Heart Center, Tampere, Finland; §Université Paris-Diderot, Paris, France; ‖University of Adelaide, Royal Adelaide Hospital, Adelaide, Australia; ¶Hopital Pasteur, Nice, France; #Southlake Regional Health Centre, University of Toronto, Ontario, Canada; **Skane University Hospital, Lund, Sweden; ††Charles University, Hospital Kralovske Vinohrady, Prague, Czech Republic; and the ‡‡St. Michael's Hospital, University of Toronto, Ontario, Canada. The Population Health Research Institute has received research support from sanofi-aventis, Bristol-Myers Squibb, and Medtronic. Dr. Jolly has received consulting fees (modest) from sanofi-aventis, GlaxoSmithKline, and AstraZeneca. Dr. Cairns has recently chaired or been a member of the data and safety monitoring board of the following industry-sponsored trials: PALLAS (sanofi-aventis), ACTIVE (sanofi-aventis), and AVERROES (Bristol-Myers Squibb); has served as a consultant to Boehringer Ingelheim Canada; and is a member of the steering committee of the TOTAL trial, which receives funding from Medtronic. Dr. Steg has received research support from sanofi-aventis and Servier; has served as a consultant and received honoraria (modest) from Astellas, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Daiichi Sankyo-Lilly, GlaxoSmithKline, Merck, Otsuka, Roche, sanofi-aventis, Servier, and The Medicines Company; and owns stock options in Aterovax. Dr. Mehta has received consulting fees/honoraria (modest) from Abbott Vascular, sanofi-aventis, Eli Lilly, and AstraZeneca. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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Unlike a new drug therapy, a procedural or surgical innovation is likely dependent on the skill and experience of the physicians performing the technique. Accordingly, the Consolidated Standards of Reporting Trials (CONSORT) guidelines recommend that all randomized trials of nonpharmacological interventions collect data and perform analyses based on procedural volume (1).

Greater percutaneous coronary intervention (PCI) procedural volume has been linked to improved clinical outcomes in studies reporting primarily femoral access (2,3). These data have led to the American College of Cardiology, American Heart Association, and Society of Cardiac Angiography and Intervention guidelines recommending a minimum of 75 PCI procedures per year for an interventional cardiologist to enhance patient safety (4). However, radial access is technically more challenging and may have a longer learning curve and require higher volumes to achieve and maintain proficiency (5). With rapidly increasing use of radial access, it is important to understand the relationship between procedural volume and outcomes with this technique.

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The RIVAL (RadIal Vs. femorAL) trial randomized 7,021 patients with acute coronary syndromes (ACS) to radial versus femoral access for coronary angiography and intervention (6,7). The trial showed no difference between radial and femoral access for the primary outcome of death, myocardial infarction (MI), stroke, or non–coronary artery bypass graft surgery (CABG)–related major bleeding, but radial access was associated with a statistically significant 63% reduction in major vascular complications. In the subgroup of high-volume radial centers the primary outcome was reduced by radial versus femoral access, but it was not reduced in intermediate- or low-volume radial centers. There was no significant interaction by individual operator radial volume.

The objective of the present analyses is to explore in greater depth the interaction between procedural volumes and access site for various outcomes in the RIVAL trial.

Methods

Study design. The design of the RIVAL trial has been previously published (6). It was a prospective randomized trial among patients with acute coronary syndromes comparing radial versus femoral access for coronary angiography and same sitting PCI if clinically indicated. Between June 6, 2006, and November 3, 2010, 7,021 patients were enrolled from 158 hospitals in 32 countries.

Patients were eligible for the study if: 1) they presented with non–ST-segment or ST-segment elevation ACS; 2) they were to be managed with an invasive approach; 3) the interventional cardiologist was willing to proceed with either radial or femoral approach (and had expertise with both, including at least 50 radial procedures within the previous year); and 4) the patient had intact dual circulation of the hand documented by Allen's test. Patients were not eligible if they presented with cardiogenic shock, had severe peripheral vascular disease precluding a femoral approach, or had prior coronary bypass surgery with use of more than 1 internal mammary artery.

Abbreviations and Acronyms

ACS = acute coronary syndrome(s)
CABG = coronary artery bypass graft
CI = confidence interval
HR = hazard ratio
MI = myocardial infarction
NSTEACS = non–ST-segment elevation acute coronary syndromes
PCI = percutaneous coronary intervention
STEMI = ST-segment elevation myocardial infarction

The primary outcome was the composite of death, MI, stroke, or non–CABG-related major bleeding. Each center was required to report the number of overall, radial, and femoral procedures per year for participating operators. At each center, the median operator volume for a center was calculated and used to classify center volume because overall center volume was not collected.

Statistical analyses. Centers were divided into tertiles according to the median radial PCI volume of their operators: (low [≤60 radial PCI/year/operator], intermediate [61 to 146 radial PCI/year/operator], and high [>146 radial PCI/year/operator]). The tertile analysis for center and operator volume was pre-specified.

Baseline characteristics and cointerventions were documented for the tertiles of low-, intermediate-, and high-volume radial centers (Table 1). The hazard ratios of radial versus femoral access for the primary outcome and secondary outcomes were compared within these tertiles.

ST-segment elevation MI and center volume. High-volume radial centers enrolled significantly higher proportion of ST-segment elevation myocardial infarction (STEMI). Interactions were observed with benefit of radial access in both STEMI subgroup and high-volume radial centers. As a result, an adjusted analysis was performed using the diagnosis of STEMI prior to randomization in a Cox proportional hazards model to help determine the independent effect of volume apart from STEMI (8).

For operator-level data instead of center-level analyses, operators were divided into tertiles according to individual operator radial PCI volume: (low [≤70 radial PCI/year/operator], intermediate [71 to 142 radial PCI/year/operator], high [>142 radial PCI/year/operator]). The hazard ratios (HRs) for the primary and secondary outcomes were compared within these tertiles. Finally, for both center and operator tertiles, stratified analyses for STEMI and non–ST-segment elevation acute coronary syndromes (NSTEACS) were performed.

All analyses were by intention to treat, unless otherwise specified. For subgroup analyses, HRs and 95% confidence intervals (CIs) and interaction p values were calculated. Statistical interactions were evaluated at a significance level of 0.05 with no adjustment made for multiple comparisons.