

Influence of Arterial Access Site Selection on Outcomes in Primary Percutaneous Coronary Intervention

Are the Results of Randomized Trials Achievable in Clinical Practice?

Mamas A. Mamas, BM BCH, DPHIL,*† Karim Ratib, MB BS,‡ Helen Routledge, MD,§ Ludwig Neyses, MD,*† Douglas G. Fraser, MB BCHIR, MD,* Mark de Belder, MA, MD,|| Peter F. Ludman, MA, MD,¶ Jim Nolan, MD,‡ on behalf of the British Cardiovascular Intervention Society and the National Institute for Cardiovascular Outcomes Research

Manchester, Stoke-on-Trent, Worcester, Middlesbrough, and Birmingham, United Kingdom

Objectives This study sought to investigate the influence of access site utilization on mortality, major adverse cardiac and cardiovascular events (MACCE), bleeding, and vascular complications in a large number of patients treated by primary percutaneous coronary intervention (PPCI) in the United Kingdom over a 5-year period, through analysis of the British Cardiovascular Intervention Society database.

Background Despite advances in antithrombotic and antiplatelet therapy, bleeding complications remain an important cause of morbidity and mortality in patients with acute ST-segment elevation myocardial infarction (STEMI) undergoing PPCI. A significant proportion of such bleeding complications are related to the access site, and adoption of radial access may reduce these complications. These benefits have not previously been studied in a large unselected national population of PPCI patients.

Methods Mortality (30-day), MACCE (a composite of 30-day mortality and in-hospital myocardial re-infarction, target vessel revascularization, and cerebrovascular events), and bleeding and access site complications were studied based on transfemoral access (TFA) and transradial access (TRA) site utilization in PPCI STEMI patients. The influence of access site selection was studied in 46,128 PPCI patients; TFA was used in 28,091 patients and TRA in 18,037. Data were adjusted for potential confounders using Cox regression that accounted for the propensity to undergo radial or femoral approach.

Results TRA was independently associated with a lower 30-day mortality (hazard ratio [HR]: 0.71, 95% confidence interval [CI]: 0.52 to 0.97; $p < 0.05$), in-hospital MACCE (HR: 0.73, 95% CI: 0.57 to 0.93; $p < 0.05$), major bleeding (HR: 0.37, 95% CI: 0.18 to 0.74; $p < 0.01$), and access site complications (HR: 0.38, 95% CI: 0.19 to 0.75; $p < 0.01$).

Conclusions This analysis of a large number of PPCI procedures demonstrates that utilization of TRA is independently associated with major reductions in mortality, MACCE, major bleeding, and vascular complication rates. (J Am Coll Cardiol Intv 2013;6:698–706) © 2013 by the American College of Cardiology Foundation

From the *Manchester Heart Centre, Manchester Royal Infirmary, Manchester, United Kingdom; †Cardiovascular Institute, University of Manchester, Manchester, United Kingdom; ‡University Hospital of North Staffordshire, Stoke-on-Trent, United Kingdom; §Worcestershire Royal Hospital, Worcester, United Kingdom; ||The James Cook University Hospital, Middlesbrough, United Kingdom; and ¶Queen Elizabeth Hospital, Birmingham, United Kingdom. Dr. de Belder has received speaker's fees from Boehringer Ingelheim and Cordis. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received December 27, 2012; revised manuscript received March 6, 2013, accepted March 15, 2013.

Primary percutaneous coronary intervention (PPCI) represents the current gold standard reperfusion strategy in the setting of acute ST-segment elevation myocardial infarction (STEMI) (1,2). Advances in antithrombotic therapy have improved the prognosis of patients presenting with STEMI by reducing ischemic events and mortality (3), although this has been at the expense of increased procedure-related bleeding complications. Such procedure-related bleeding complications are independently associated with adverse events, including 30-day mortality, reinfarction, and stroke (4–6). Recent studies evaluating new antithrombotic therapies have focused on the reduction of bleeding events as a major therapeutic goal (7–9). Patients with STEMI undergoing percutaneous coro-

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nary intervention (PCI) are at high risk for the development of such bleeding complications. For example, data from the National Heart, Lung, and Blood Institute Dynamic Registry have documented a significant increase in bleeding and transfusions in patients presenting with STEMI compared with those with non-STEMI (10). A significant proportion of these major bleeding complications are related to the access site (11), and adoption of the transradial access (TRA) site in patients undergoing PCI has been shown to reduce access site-related bleeding complications in selected populations (12).

The recent randomized controlled trial RIFLE-STEACS (Radial versus Femoral Randomized Investigation in ST Elevation Acute Coronary Syndrome) suggests that adoption of the transradial route may be associated with a reduction in cardiac mortality, MACCE (major adverse cardiac and cerebrovascular events), and access site-related bleeding complications in patients presenting with STEMI (13), whereas a recent meta-analysis of randomized controlled studies suggested that the TRA is associated with a 47% reduction in mortality and a 38% reduction in major adverse cardiac events in STEMI patients undergoing PCI (14). These randomized controlled trials that have studied the influence of access site on outcomes in patients undergoing STEMI PCI are relatively small in size and have excluded many high-risk patient groups such as those presenting with cardiogenic shock (15–19), elderly patients (15), and those with previous coronary artery bypass grafting (CABG) (15–18), hence, the applicability of such data to real-world practice remains unclear. Furthermore, previous data derived from randomized controlled studies in STEMI PCI patients often include a significant proportion of rescue and facilitated PCI cases (16,17,19), hence, its applicability to the PPCI setting remains uncertain. We have therefore analyzed outcomes from a large observational database of primary PCI cases performed in the United Kingdom over a 5-year period, to investigate the relationship between access site practice and

outcomes in a nonselected, high-risk, real-world cohort of patients.

Methods

The British Cardiovascular Intervention Society database. The British Cardiovascular Intervention Society (BCIS) was formed in 1988 to collect PCI data relating to the nationwide practice of PCI in the United Kingdom. From 1988 to 1991, annual national PCI data were published in the *British Heart Journal* whereas annual reports from 1992 onwards are available for download from the society's website. The data are collected via the Central Cardiac Audit Database (20) under the auspices of the National Institute of Cardiovascular Outcomes Research (NICOR). The aim of the BCIS-NICOR database is to record all PCI procedures performed in any hospital in the United Kingdom (England, Scotland, Wales, and Northern Ireland). In 2009, 97% of all PCI procedures performed in National Health Service hospitals in England and Wales had been entered into the database.

The BCIS-NICOR database records clinical, procedural, and outcome information with a total of 113 variables collected and available in the form of an Excel spreadsheet (Microsoft, Redmond, Washington). Information recorded in the database includes patient demographic features, indications for PCI, procedural details, and outcome data (20). As of March 2010, there were approximately 460,000 records in the BCIS database, with approximately 80,000 new records being added each year. Mortality tracking is undertaken by the Medical Research Information Service using patients' National Health Service number that provides a unique identifier for any person registered with the National Health Service in England and Wales.

Study definitions. PPCI procedures performed in patients presenting with STEMI in the United Kingdom between January 1, 2006, and December 31, 2010, were analyzed in this study. Patients who underwent PCI through the left or right femoral artery or the left or right radial artery were included in the femoral and radial cohorts, respectively. The primary outcomes examined were 30-day mortality and

Abbreviations and Acronyms

AMI	= acute myocardial infarction
BCIS	= British Cardiovascular Intervention Society
CABG	= coronary artery bypass grafting
CI	= confidence interval
GP	= glycoprotein
HR	= hazard ratio
IABP	= intra-aortic balloon pump
MACCE	= major adverse cardiac and cerebrovascular event(s)
OR	= odds ratio
PCI	= percutaneous coronary intervention
PPCI	= primary percutaneous coronary intervention
STEMI	= ST-segment elevation myocardial infarction
TFA	= transfemoral access
TRA	= transradial access

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