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Baseline Bleeding Risk and Arterial Access Site Practice in Relation to Procedural Outcomes After Percutaneous Coronary Intervention

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ABSTRACT

BACKGROUND Transradial access (TRA) has been associated with reduced access site-related bleeding complications and mortality after percutaneous coronary intervention (PCI). It is unclear, however, whether these observed benefits are influenced by baseline bleeding risk.

OBJECTIVES This study investigated the relationship between baseline bleeding risk, TRA utilization, and procedure-related outcomes in patients undergoing PCI enrolled in the British Cardiovascular Intervention Society database.

METHODS Baseline bleeding risk was calculated by using modified Mehran bleeding risk scores in 348,689 PCI procedures performed between 2006 and 2011. Four categories for bleeding risk were defined for the modified Mehran risk score (MMRS): low (<10), moderate (10 to 14), high (15 to 19), and very high (≥20). The impact of baseline bleeding risk on 30-day mortality and its relationship with access site were studied.

RESULTS TRA was independently associated with a 35% reduction in 30-day mortality risk (odds ratio [OR]: 0.65 [95% confidence interval (CI): 0.59 to 0.72]; $p < 0.0001$), with the magnitude of mortality reduction related to baseline bleeding risk (MMRS <10, OR: 0.73 [95% CI: 0.62 to 0.86]; MMRS ≥20, OR: 0.53 [95% CI: 0.47 to 0.61]). In patients with an MMRS <10, TRA was used in 71,771 (43.2%) of 166,083 PCI procedures; TRA was used in 8,655 (40.1%) of 21,559 PCI procedures in patients with an MMRS ≥20, illustrating that TRA was used less in those at highest risk from bleeding complications ($p < 0.0001$).

CONCLUSIONS TRA was independently associated with reduced 30-day mortality, and the magnitude of this effect was related to baseline bleeding risk; those at highest risk of bleeding complications gained the greatest benefit from adoption of TRA during PCI. (J Am Coll Cardiol 2014;64:1554–64) © 2014 by the American College of Cardiology Foundation.

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Advances in antithrombotic therapy have improved outcomes for patients undergoing percutaneous coronary intervention (PCI) by reducing ischemic events and mortality but with a corresponding increase in procedure-related bleeding complications. These peri-procedural bleeding complications are associated with adverse clinical outcomes, including myocardial infarction (MI), stroke, and death (1–3).

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A significant proportion of such major bleeding complications are related to the access site. In a post-hoc analysis of the REPLACE-2 (Randomized Evaluation in PCI Linking Angiomax to Reduced Clinical Events), ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy), and HORIZONS-AMI (Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction) trials, 38.6% of major bleeds were access site related (4), and in the RIVAL (Radial vs. Femoral Access for Coronary Intervention) study, 30% of non-coronary artery bypass graft (CABG)-related major bleeds were access site related (5). A proportion of these access site bleeds correlate to the patients' syndrome at presentation; patients with ST-segment elevation myocardial infarction (STEMI) exhibit a higher incidence of bleeding and a higher proportion of access site bleeds than those with non-ST-segment elevation myocardial infarction (NSTEMI) or unstable angina (6).

Transradial access (TRA) has been adopted as the default approach for PCI in many European and North American centers because of its proven beneficial effect on access site-related complications and mortality (6–8). It is widely believed that the mortality benefits seen with TRA are mediated through a reduction in major bleeding complications (9–11). A recent subgroup analysis of the RIVAL study found that TRA significantly reduces mortality as well as the primary composite outcome of mortality, MI, stroke, and non-CABG-related major bleeding in the STEMI subgroup; non-CABG major bleeding was not affected (12). In contrast, TRA was not associated with any impact on these outcomes in the NSTEMI cohort (12).

This finding may be related to the underlying bleeding risk in these patient groups. For example, 30-day Thrombolysis In Myocardial Infarction (TIMI) major bleeding increased from 0.7% in patients with stable angina to 1.6% and 2.6% in the NSTEMI and STEMI groups, respectively, in a recent patient-level pooled analysis of the REPLACE-2 (Randomized Evaluation of PCI Linking Angiomax to Reduced Clinical Events), ACUITY (Acute Catheterization and Urgent Intervention Triage strategY), and HORIZONS-AMI (Harmonizing Outcomes with Revascularization and Stents in Acute Myocardial Infarction) studies (13). Similarly, major bleeding increased from 1.1% in patients with stable angina to 1.8% and 4.5% in the NSTEMI and STEMI groups in an analysis of the National Cardiovascular Data Registry known as CathPCI (14). It is therefore possible that the greatest benefit of TRA occurs in those patients at greatest risk from bleeding complications, although previous research has not systematically studied the influence of baseline bleeding risk on access site-related outcomes.

The present paper is an observational analysis of TRA versus transfemoral access (TFA) utilization and their associated outcomes in a nonselected national cohort derived from the British Cardiovascular Intervention Society (BCIS) database over a 6-year period. We aimed to study the impact of baseline peri-procedural bleeding risk on access site-related outcomes and whether baseline bleeding risk influences access site choice within the United Kingdom.

ABBREVIATIONS AND ACRONYMS

BCIS = British Cardiovascular Intervention Society
CABG = coronary artery bypass graft
CI = confidence interval
MI = myocardial infarction
NHS = National Health Service
NSTEMI = non-ST-segment elevation myocardial infarction
OR = odds ratio
PCI = percutaneous coronary intervention
STEMI = ST-elevation myocardial infarction
TFA = transfemoral access
TIMI = Thrombolysis In Myocardial Infarction
TRA = transradial access

METHODS

THE BCIS DATABASE. The BCIS collects data relating to the United Kingdom's nationwide practice of PCI (15). The data are collected via the Central Cardiac Audit Database under the auspices of the National Institute for Cardiovascular Outcomes Research. The aim is to record all PCI procedures performed in any U.K. hospital. In 2011, ~99% of all PCI procedures performed in U.K. National Health Service (NHS) hospitals had been entered into the database.

The BCIS database documents clinical, procedural, and outcomes information with a total of 113 variables. As of December 2011, there were ~459,775 records in the BCIS database, with ~80,000 new records added each year. Mortality tracking is performed by the Medical Research Information Service by using each patient's NHS number, which provides a unique identifier for any person registered with the NHS in England and Wales.

STUDY DEFINITIONS. The data presented relate to all reported PCI procedures undertaken in patients in the United Kingdom between January 1, 2006, and December 31, 2011. PCI procedures performed via the left or right femoral artery or the left or right radial