The Learning Curve for Transradial Percutaneous Coronary Intervention Among Operators in the United States
A Study From the National Cardiovascular Data Registry

Connie N. Hess, MD, MHS; Eric D. Peterson, MD, MPH; Megan L. Neely, PhD; David Dai, PhD; William B. Hillegass, MD; Mitchell W. Krucoff, MD; Michael A. Kutcher, MD; John C. Messenger, MD; Samir Pancholy, MD; Robert N. Piana, MD; Sunil V. Rao, MD

Background—Adoption of transradial percutaneous coronary intervention (TRI) in the United States is low and may be related to challenges learning the technique. We examined the relationships between operator TRI volume and procedural metrics and outcomes.

Methods and Results—We used CathPCI Registry data from July 2009 to December 2012 to identify new radial operators, defined by an exclusively femoral percutaneous coronary intervention approach for 6 months after their first percutaneous coronary intervention in the database and ≥15 total TRIs thereafter. Primary outcomes of fluoroscopy time, contrast volume, and procedure success were chosen as markers of technical proficiency. Secondary outcomes included in-hospital mortality, bleeding, and vascular complications. Adjusted outcomes were analyzed by using operator TRI experience as a continuous variable with generalized linear mixed models. Among 54,561 TRI procedures performed at 704 sites, 942 operators performed 1 to 10 procedures, 942 operators performed 11 to 50 procedures, 375 operators performed 51 to 100 procedures, and 148 operators performed 101 to 200 procedures. As radial caseload increased, more TRIs were performed in women, in patients presenting with ST-segment elevation myocardial infarction, and for emergency indications. Decreased fluoroscopy time and contrast use were nonlinearly associated with greater operator TRI experience, with faster reductions observed for newer (<30–50 cases) compared with more experienced (>30–50 cases) operators. Procedure success was high, whereas mortality, bleeding, and vascular complications remained low across TRI volumes.

Conclusions—As operator TRI volume increases, higher-risk patients are chosen for TRI. Despite this, operator proficiency improves with greater TRI experience, and safety is maintained. The threshold to overcome the learning curve appears to be approximately 30 to 50 cases. (Circulation. 2014;129:2277-2286.)

Key Words: learning curve ■ percutaneous coronary intervention

Radial artery access for percutaneous coronary intervention (PCI) has potential advantages over the femoral approach. Compared with transfemoral PCI, transradial PCI (TRI) has been associated with reduced access site bleeding, fewer vascular complications, shorter hospital length of stay, and a trend toward reduced mortality in patients with ST-segment elevation myocardial infarction (STEMI). The transradial approach is also preferred by patients over the femoral route.3 Despite these potential benefits, TRI has been associated with increased radiation exposure, greater contrast use, and higher rates of procedural failure. Overall rates of TRI use in this country remain low at 10% to 16% of PCI procedures. Furthermore, TRI use in the United States has been associated with a risk-treatment paradox whereby high-risk patients who may benefit the most from the radial approach are least likely to undergo TRI.10,11

Challenges associated with TRI and low uptake of this technology may be related in part to the technical proficiency for new operators. The concept of a learning curve, in which operator skill improves with greater experience, has been observed for many procedures, including TRI. Clinical trials and observational studies have reported no difference between TRI and transfemoral PCI, with the exception of centers with proficient radial operators. To date, attempts to quantify the association between TRI experience and operator proficiency have been predominantly performed in small, single-center studies conducted outside the United States. Determining the minimum threshold to overcome the learning curve could be

Received September 18, 2013; accepted March 10, 2014.

From the Duke Clinical Research Institute, Durham, NC (C.N.H., E.D.P., M.L.N., D.D., M.W.K., S.V.R.); University of Alabama at Birmingham, Birmingham, AL (W.B.H.); Wake Forest University School of Medicine, Winston-Salem, NC (M.A.K.); University of Colorado, Denver, CO (J.C.M.); The Wright Center for Graduate Medical Education, Scranton, PA (S.P.); Vanderbilt Heart Center, Nashville, TN (R.N.P.).

The online-only Data Supplement is available with this article at http://circ.ahajournals.org/lookup/suppl/doi:10.1161/CIRCULATIONAHA.113.006356/-/DC1.

Correspondence to Connie N. Hess, MD, MHS, Duke University Medical Center, Duke Clinical Research Institute, 2400 Pratt St, Room 0311, Terrace Level, Durham, NC 27705. E-mail connie.hess@duke.edu

© 2014 American Heart Association, Inc.

Circulation is available at http://circ.ahajournals.org

DOI: 10.1161/CIRCULATIONAHA.113.006356
important for facilitating TRI adoption in the United States, improving patient outcomes, and informing training guidelines and clinical trials of TRI. Therefore, we sought to (1) characterize the changes in patient selection for TRI procedures according to radial experience; (2) examine the relationship between TRI volume and procedural outcomes, including fluoroscopy time, contrast use, and procedural success; and (3) assess the relationship between TRI volume and in-hospital outcomes among US operators by the use of data from the National Cardiovascular Data Registry CathPCI Registry.

Methods

Data Source

Details about the CathPCI Registry have been previously described. In brief, the CathPCI Registry is an initiative of the American College of Cardiology and The Society for Cardiovascular Angiography and Interventions. As the nation’s largest PCI registry, the CathPCI Registry provides clinical and procedural data on patients undergoing cardiac catheterization and PCI from >1400 US hospitals. Trained data abstractors collect patient and procedural information at each participating institution via chart review by using a standardized set of data elements and definitions (http://www.ncdr.com/WebNCDR/cathpci/home/datacollection). Data quality is assured via automatic system validation and reporting of data completeness, random on-site audits, and site data manager training.

Study Population

We examined 2242253 PCI procedures performed by 9304 operators at 1397 sites between July 2009 and December 2012 with data reported by using version 4 of the CathPCI Registry collection form (Figure 1). PCIs with missing data regarding route of vascular access (n=22,209) and femoral PCIs (n=2007.729) were excluded. We included new transradial operators (n=28,044), defined as those with a period of no TRI procedures but at least 1 femoral PCI per calendar reporting quarter for 6 months (blanking period) after the operator’s first femoral PCI in CathPCI Registry version 4 data (Figure 2). A TRI case volume of <15 cases proved insufficient to accurately estimate a learning curve. As a result, new radial operators performing <15 total TRIs (n=7370 TRIs; 1860 operators) were excluded, and modeling of the early learning curve (1st to 14th cases) was performed by using data from operators included in our analysis (≥15 total TRIs). Data from the >200th case TRI procedures for high-volume operators (n=3434 TRIs) were also excluded owing to insufficient operators to accurately model the learning curve in this range. However, these high-volume operators were not excluded from our study, as they contributed data from their first 200 TRI cases to our analyses. Our final analysis population consisted of 54561 TRI procedures performed by 942 radial operators at 704 sites.

Definitions and Outcomes

The following primary outcomes for our study were chosen as markers of operator proficiency: fluoroscopy time, contrast volume used, and procedure success. Procedure success is defined in the registry as residual stenosis ≤50% with a Thrombolysis in Myocardial Infarction flow grade ≥2 and at least 20% decrease in stenosis severity. For multivessel PCI procedures, procedure success was considered present if the number of lesions attempted and successfully dilated were equal. Since CathPCI Registry does not capture access site crossover, we were unable to assess procedure success via the initial access site without crossover. Secondary outcomes included in-hospital mortality, vascular complications, access site bleeding or hematoma, and any bleeding event within 72 hours post-PCI. Bleeding was defined as arterial access site bleeding—either overt, external bleeding, or a forearm hematoma >2 cm; retroperitoneal, gastrointestinal, or genitourinary bleeding; intracranial hemorrhage; cardiac tamponade; decrease in hemoglobin post-PCI in patients with preprocedure hemoglobin ≤16 g/dl; or postprocedure nonbypass surgery–related blood transfusion in patients with a pre-PCI hemoglobin of ≤8 g/dl.

Statistical Analysis

Radial volume was analyzed as a continuous variable for modeling, but to characterize patient and procedural features for descriptive purposes, the following categories of operator TRI volume were used: 1st to 10th, 11th to 50th, 51st to 100th, and 101th to 200th cases. These groupings represent running tallies of TRI experience such that operators can contribute to >1 group and serve as their own controls; this approach allows for assessments of average changes in patient selection and procedural metrics over individual learning curves. Categorical variables were presented as frequencies and percentages, and continuous variables were summarized as medians with interquartile ranges. Comparisons among categorical and continuous variables were performed by using the Pearson χ² and Kruskal-Wallis tests, respectively. Observed rates of the primary and secondary outcomes were reported according to operator TRI experience. We also compared observed rates with predicted bleeding rates by using the CathPCI Registry PCI bleeding risk model applied to patients in categories of operator TRI volume.

To examine the relationship between radial case volume and outcomes, generalized linear mixed models (linear regression for the continuous outcomes of fluoroscopy time and contrast volume; logistic regression for the categorical outcome of procedure success) were developed by using radial case volume as a continuous variable. Relationships were plotted as curves for outcome versus TRI case volume such that any given slope along the curve represents the rate of change in outcome with increasing TRI experience. Restricted cubic splines were used to explore potential nonlinear relationships between case volume and outcomes, with random effects placed on the intercept and slopes for each component of the restricted cubic spline for case volume, assuming an unstructured covariance matrix. Intraoperator clustering of radial case volume was accounted for in the mixed models through the use of an autoregressive (order 1) covariance matrix that assumes that radial procedures performed closer to each other are likely to be more similar with respect to operator-level effects than those performed further apart. This mixed model also accounts for operator-specific effects such as case-mix selection. Analyses were repeated after adjustment for the following variables: age, female sex, body mass index, diabetes mellitus, cerebrovascular disease, peripheral vascular disease, chronic lung disease, glomerular filtration rate, previous PCI, New York Heart Association class, ejection fraction, cardiogenic shock, presentation with STEMI,
To determine the threshold for overcoming the learning curve, the presence of potential inflection points along the relationship curves between case volume (per case increase) and outcomes by fitting linear splines by using a single knot point was tested. Candidate knot points were chosen for testing based on visual inspection of curves. Given that linear splines with a single knot are less flexible than the restricted cubic spline methodology used for the primary analysis, similar Akaike Information Criterion values ensured that the fit of data by using linear versus cubic splines was comparable. The slopes of the curve before versus after the knot point were compared by using score tests. In this approach, the slope of the curve indicates the rate and magnitude of change of the outcome of interest as TRI volume increases, and a significant difference between the pre- versus postknot slopes indicates that the knot point can be considered an inflection point along the curve. Finally, prespecified sensitivity analyses were performed after additionally adjusting for previous femoral PCI experience, defined as the cumulative number of femoral PCI procedures performed during the study period before the TRI procedure being modeled, and in high-risk subgroups including females and patients ≥75 years of age. Analyses could not be repeated in patients undergoing TRI for STEMI (n=3798) because of the small sample size and the lack of convergence of our statistical models. For all analyses, P values of <0.05 were considered statistically significant without correction for multiple comparisons. All analyses were performed at the Duke Clinical Research Institute using SAS software (version 9.2, SAS Institute, Cary, NC).

Results

Operator TRI Volume

After exclusions (Figure 1), 54,561 TRI procedures performed by 942 new radial operators at 704 sites were included in our analysis. The distribution of TRI volume among operators is shown in Figure 3. The median total number of TRI procedures performed by individual operators during our study period was 40, and the 25th and 75th percentiles for TRI experience were 23 and 78 procedures, respectively.
Patient and Procedure Characteristics

Overall, the median age of patients undergoing TRI was 63 years (interquartile range, 55–71), 29.7% (n=16,182) of patients were female, and 7.0% (n=3,798) of patients presented with STEMI. Among the total study cohort, 89.7% (n=48,920) of TRIs were performed at the same time as diagnostic angiography (ad hoc). TRIs were performed for emergency indications in 7.9% (n=4,315), in multiple vessels in 11.3% (n=6,159), and for high-complexity lesions in 52.2% (n=28,442). Patient and procedure characteristics were examined according to categories of operator TRI volume (Tables 1 and 2). As TRI volume increased, more females, patients with New York Heart Association class IV heart failure, patients presenting with STEMI, and patients with higher bleeding risk

<table>
<thead>
<tr>
<th>Table 1. Patient Characteristics According to TRI Case Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline clinical characteristics</strong></td>
</tr>
<tr>
<td>Age, median (IQR), y</td>
</tr>
<tr>
<td>Female, %</td>
</tr>
<tr>
<td>Race/ethnicity, %</td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td>Black</td>
</tr>
<tr>
<td>Hispanic</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Weight, median (IQR), kg</td>
</tr>
<tr>
<td>Height, median (IQR), cm</td>
</tr>
<tr>
<td>BMI, median (IQR), kg/m²</td>
</tr>
<tr>
<td>Current/recent smoker, %</td>
</tr>
<tr>
<td>Hypertension, %</td>
</tr>
<tr>
<td>Dyslipidemia, %</td>
</tr>
<tr>
<td>Cerebrovascular disease, %</td>
</tr>
<tr>
<td>Peripheral artery disease, %</td>
</tr>
<tr>
<td>Chronic lung disease, %</td>
</tr>
<tr>
<td>Diabetes mellitus, %</td>
</tr>
<tr>
<td>Prior MI, %</td>
</tr>
<tr>
<td>Prior PCI,* %</td>
</tr>
<tr>
<td>Prior CABG, %</td>
</tr>
<tr>
<td>Prior CHF, %</td>
</tr>
<tr>
<td>GFR, median (IQR)</td>
</tr>
<tr>
<td>Admission symptoms, %</td>
</tr>
<tr>
<td>No angina</td>
</tr>
<tr>
<td>Atypical chest pain</td>
</tr>
<tr>
<td>Stable angina</td>
</tr>
<tr>
<td>Unstable angina</td>
</tr>
<tr>
<td>NSTEMI</td>
</tr>
<tr>
<td>STEMI</td>
</tr>
<tr>
<td>CHF/NYHA class within 2 wk, %</td>
</tr>
<tr>
<td>No CHF</td>
</tr>
<tr>
<td>I</td>
</tr>
<tr>
<td>II</td>
</tr>
<tr>
<td>III</td>
</tr>
<tr>
<td>IV</td>
</tr>
<tr>
<td>Median predicted bleeding, % (IQR)</td>
</tr>
</tbody>
</table>

**BMI** indicates body mass index; **CABG**, coronary artery bypass grafting; **CHF**, congestive heart failure; **GFR**, glomerular filtration rate; **IQR**, interquartile range; **MI**, myocardial infarction; **NSTEMI**, non–ST-segment elevation myocardial infarction; **NYHA**, New York Heart Association; **PCI**, percutaneous coronary intervention; **STEMI**, ST-segment elevation myocardial infarction; and **TRI**, transradial percutaneous coronary intervention.

*All P values are <0.05 unless marked by an asterisk.
were selected to undergo PCI with the use of a radial versus femoral approach. Operators also performed more emergent PCIs, multivessel PCIs, and technically complex PCIs as they gained experience with TRI.

**Outcomes According to TRI Volume**

Overall, the median observed procedure fluoroscopy time was 14.3 minutes (interquartile range, 9.6–21.3), and the median observed contrast volume used was 180.0 mL (interquartile range, 131.0–230.0) per TRI. The rate of overall procedure success was high (96.0%, n=51,636). Ad hoc TRI procedures had greater median fluoroscopy times (14.6 versus 11.4 minutes; \( P<0.001 \)) and median contrast use (180 versus 130 mL; \( P<0.001 \)), but similar procedure success rates (95.9% versus 96.5%; \( P=0.05 \)) in comparison with scheduled TRI procedures. As shown in Table 3, observed median fluoroscopy times and contrast use for all procedures decreased significantly with increasing operator TRI volume (\( P<0.001 \)). Despite more complex patient case-mix with greater TRI experience, procedure success remained consistently high across categories of TRI experience (\( P=0.44 \)). Among patients with multivessel disease and without previous coronary artery bypass grafting, there was no substantial difference in the proportion of successfully

### Table 2. Procedure Characteristics According to TRI Case Volume

<table>
<thead>
<tr>
<th>Category</th>
<th>1–10 (n=9420 TRIs; 942 operators)</th>
<th>11–50 (n=25,253 TRIs; 942 operators)</th>
<th>51–100 (n=12,432 TRIs; 375 operators)</th>
<th>101–200 (n=7,456 TRIs; 148 operators)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCI status, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elective</td>
<td>52.5</td>
<td>47.3</td>
<td>44.0</td>
<td>43.3</td>
</tr>
<tr>
<td>Urgent</td>
<td>43.1</td>
<td>45.7</td>
<td>46.0</td>
<td>44.6</td>
</tr>
<tr>
<td>Emergent/salvage</td>
<td>4.3</td>
<td>7.0</td>
<td>9.9</td>
<td>12.2</td>
</tr>
<tr>
<td>Number of diseased vessels, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>53.9</td>
<td>54.1</td>
<td>51.5</td>
<td>50.9</td>
</tr>
<tr>
<td>2</td>
<td>32.3</td>
<td>32.3</td>
<td>33.6</td>
<td>33.0</td>
</tr>
<tr>
<td>3</td>
<td>13.7</td>
<td>13.6</td>
<td>15.0</td>
<td>16.0</td>
</tr>
<tr>
<td>Number of treated lesions, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>76.8</td>
<td>75.9</td>
<td>74.7</td>
<td>74.7</td>
</tr>
<tr>
<td>2</td>
<td>18.7</td>
<td>19.8</td>
<td>20.6</td>
<td>20.9</td>
</tr>
<tr>
<td>3+</td>
<td>4.5</td>
<td>4.3</td>
<td>4.7</td>
<td>4.5</td>
</tr>
<tr>
<td>Multivessel PCI, %</td>
<td>10.7</td>
<td>11.1</td>
<td>11.5</td>
<td>12.5</td>
</tr>
<tr>
<td>Previously treated lesion, %</td>
<td>10.3</td>
<td>10.8</td>
<td>11.4</td>
<td>11.4</td>
</tr>
<tr>
<td>High lesion complexity (high/C), %</td>
<td>49.4</td>
<td>51.2</td>
<td>53.9</td>
<td>56.4</td>
</tr>
<tr>
<td>Bifurcation lesion, %</td>
<td>11.4</td>
<td>12.3</td>
<td>13.7</td>
<td>12.4</td>
</tr>
<tr>
<td>Thrombus present, %</td>
<td>7.5</td>
<td>10.4</td>
<td>12.9</td>
<td>13.4</td>
</tr>
<tr>
<td>Saphenous vein graft PCI, %</td>
<td>2.5</td>
<td>2.2</td>
<td>2.6</td>
<td>3.4</td>
</tr>
<tr>
<td>Minimum stent diameter ≥3 mm, %</td>
<td>30.3</td>
<td>28.7</td>
<td>29.9</td>
<td>31.9</td>
</tr>
<tr>
<td>Total stent length, median (IQR)</td>
<td>36 (24–50)</td>
<td>37 (26–52)</td>
<td>38 (27–53)</td>
<td>38 (26–53)</td>
</tr>
</tbody>
</table>

All \( P \) values are <0.05. IQR indicates interquartile range; PCI, percutaneous coronary intervention; and TRI, transradial percutaneous coronary intervention.

### Table 3. Outcomes According to TRI Case Volume

<table>
<thead>
<tr>
<th>Category</th>
<th>1–10 (n=9420 TRIs; 942 operators)</th>
<th>11–50 (n=25,253 TRIs; 942 operators)</th>
<th>51–100 (n=12,432 TRIs; 375 operators)</th>
<th>101–200 (n=7,456 TRIs; 148 operators)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median fluoroscopy time, min (IQR)</td>
<td>16.0 (10.8–23.6)</td>
<td>14.6 (10.0–21.5)</td>
<td>13.5 (9.2–20.2)</td>
<td>12.6 (8.4–19.3)</td>
</tr>
<tr>
<td>Median contrast volume, mL (IQR)</td>
<td>185.0 (140.0–245.0)</td>
<td>180.0 (135.0–231.0)</td>
<td>175.0 (130.0–230.0)</td>
<td>175.0 (130.0–225.0)</td>
</tr>
<tr>
<td>Procedure success, %</td>
<td>96.2</td>
<td>96.0</td>
<td>95.8</td>
<td>96.1</td>
</tr>
<tr>
<td><strong>Secondary</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-hospital mortality, %</td>
<td>0.5</td>
<td>0.4</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Vascular complication, %</td>
<td>0.1</td>
<td>0.1</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Access site bleeding, %</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Access site hematoma, %</td>
<td>0.2</td>
<td>0.2</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Any bleeding event, %</td>
<td>2.7</td>
<td>2.2</td>
<td>2.4</td>
<td>2.0</td>
</tr>
</tbody>
</table>

IQR indicates interquartile range; and TRI, transradial percutaneous coronary intervention.
treated vessels per number of diseased vessels as operator TRI volume increased (Table I in the online-only Data Supplement). Overall rates of secondary outcomes were low for in-hospital mortality (0.5%, n=246), vascular complications (0.1%, n=79), access site bleeding (0.1%, n=45), access site hematoma (0.1%, n=81), or any observed bleeding event (2.3%, n=1221). Although patients at progressively higher risk for bleeding were selected for TRI as operator experience increased, the rate of observed bleeding remained low and trended toward less bleeding across the spectrum of operator TRI volume (Table 3).

Relationship Between TRI Volume and Outcomes

The relationship between TRI volume and procedural outcomes was assessed. After modeling, a significant nonlinear association between increasing radial volume and decreasing fluoroscopy time ($P<0.001$ for nonlinearity and association; Figure 4A) was observed. As shown in Figure 4B, TRI volume and fluoroscopy time remained significantly associated and demonstrated a nonlinear relationship after adjustment for patient and procedural characteristics. A similarly significant nonlinear association between increasing TRI volume and decreasing contrast use was observed.
In this study, almost 55\% PCI, technical challenges associated with TRI may dis-
procedure success remained consistently high across the spectrum of TRI experience, and no significant
association between TRI volume and procedural success using unadjusted or adjusted models (Figure 4E and 4F,
respectively) was found.

The presence of inflection points along the curves for fluo-
orscopy time and contrast volume was investigated (Table II in the online-only Data Supplement). Knot points between 30
and 50 TRI cases were chosen for evaluation based on visual
inspection of the plots. Similar Akaike Information Criterion
values indicated that each pair of linear splines using these
various knot points fit the data and equally as well as the main
model. For both fluoroscopy time and contrast volume, there
were statistically significant differences between pre- versus
postknot slopes at each knot point tested, indicating that each
could be considered an inflection point and that there is a
range of case volumes beyond which improvements in pro-
cedural metrics begin to flatten. Furthermore, for both out-
comes and across all knot points evaluated, the slopes before
the knots were substantially steeper and more negative than
slopes thereafter, indicating greater and faster reductions in
fluoroscopy time and contrast volume use associated with
increasing TRI volume along the earlier learning curve for
inexperienced operators (<30–50 TRI cases) compared with
the ongoing learning curve for more experienced operators
(>50 TRI cases).

Sensitivity Analyses
Several prespecified sensitivity analyses were performed. To
assess for an effect of overall PCI experience on outcomes,
alyses were repeated after including an adjustment vari-
able for previous femoral PCI volume, but did not change
the primary results. Next, a potential effect modification
of the relationship between TRI volume and outcomes in
high-risk subgroups of females and patients ≥75 years of age
was examined. In our cohort, 29.7\% (n=16,182) of TRI
procedures were performed in females, and 17.4\% (n=9,502) of
TRIs were performed in patients ≥75 years of age. Results of
analyses repeated in both of these subgroups were consistent
with our primary findings (Figures I and II in the online-only
Data Supplement).

Discussion
Despite important potential benefits of TRI over transfe-
romal PCI, technical challenges associated with TRI may dis-
courage new operators from adopting the radial approach.
In this study, almost 55,000 TRI procedures performed by
>900 US operators using data from the nation’s largest PCI
registry were examined. We found that higher-risk patients
and more complicated cases are selected for TRI as opera-
tor experience increases. In spite of this greater complexity
in case selection, rates of bleeding and vascular complica-
tions and in-hospital mortality remain low, whereas proc-
dural success rates remain high. We further demonstrate
the existence of an operator learning curve whereby procedural
metrics that are markers of operator proficiency significantly
improve with increasing TRI volume. Based on our data, the
threshold for overcoming this learning curve is ≈30 to 50
cases, though this number will likely vary for each individual
operator. These findings suggest that the learning curve
for TRI is relatively shallow with the availability of mod-
ern interventional equipment and should inform TRI train-
ing guidelines in the United States. Importantly, procedural
metrics will likely continue to improve as an operator’s TRI
experience increases.

The concept of a learning curve for TRI has previ-
ously been recognized,\textsuperscript{1,2,13,22,23} although few studies have
attempted to quantify this relationship. Spaulding et al\textsuperscript{16}
found that an annual procedural volume of >80 transradial
cases correlated with significantly lower rates of access fail-
ure and overall procedure time when using the left radial
artery approach for coronary angiography. A more recent
study examined the metrics for radial diagnostic angiograms
over 1 year for inexperienced operators and found significant
improvements in procedure time, fluoroscopy time, and contrast
use in the comparison of the results from the operators’ last 6 months of experience (n=236 proce-
dures) with their first 6 months (n=82 procedures).\textsuperscript{17} The
only learning curve analysis to specifically assess TRI pro-
cedures is based on single-center data from Canada.\textsuperscript{13} In
this study, the authors showed that a case volume threshold of at
least 50 TRI procedures was required for new radial opera-
tors to achieve similar procedural outcomes as experienced
radial performers (>300 TRIs).

The results of our study add to and extend existing data
in several ways. First, to our knowledge, this is the only
US-based multicenter study examining the TRI learning curve.
Second, this work represents the largest radial learning curve
analysis to date, incorporating data from ≈55,000 TRI proce-
dures performed by >900 operators at >700 different centers.
Consequently, these results characterize a national learning
curve based on community practice data and are generaliz-
able to the majority of US operators interested in learning to
perform TRI. Third, we used detailed clinical and procedural
CathPCI Registry data that allowed for multivariable adjust-
ment in examinations of TRI volume and operator proficiency.
The strength of these findings is supported by sensitivity anal-
yses among patient subgroups known to be at higher risk for
bleeding and vascular complications and to have more chal-
 lenging anatomy for the radial approach. Finally, the large
sample size permitted the use of rigorous statistical meth-
odology to characterize the association between procedural
outcomes and TRI volume and to test for the presence of a
threshold along the learning curve.

There were several key differences in the findings from
this analysis in comparison with those from previous stud-
ies. The previously reported threshold of 80 procedures was
based on an older analysis of diagnostic angiograms, not
TRIs, and this study predated the wide availability of dedi-
cated radial access equipment and radial training courses.
Although our threshold of 30 to 50 cases is consistent with
the minimum of 50 cases reported by Ball et al,\textsuperscript{15} in con-
trast to their findings, we did not observe that procedure suc-
cess increased with greater TRI volume. This discrepancy
is likely explained by the fact that operators in our study
selected increasingly more complex patients for TRI with
additional TRI experience, whereas no similar trend was observed in the study by Ball et al. Therefore, we hypothesize that high procedure success rates early in the learning curve were likely related to the selection of lower-risk cases, whereas consistently high procedural success despite more complex patient selection later on reflected improved operator skill. Importantly, these CathPCI Registry data support a range of potential thresholds from 30 to 50 cases, not a single threshold. This range is consistent with the idea that decisions regarding an operator’s level of proficiency and comfort with TRI and, consequently, selection of patients for TRI during the learning phase, should be made on an individual basis. As recently demonstrated, the successful adoption of TRI may ultimately require an operator to approach cases with a radial first mentality. Additionally, nonoperator-dependent factors, such as catheterization laboratory and ward staff training for preparing and caring for patients undergoing TRI or the availability of experienced mentors, need to be considered. Finally, we observed continued improvements in technical proficiency beyond the initial learning curve. This observation, which has been noted in a study of vascular complications and procedure success among experienced TRI operators, suggests that the volume-outcome relationship previously described for femoral PCIs also exists for TRI procedures.

These data have important implications for adoption of TRI in the United States and for TRI training. Data from a recent international survey show that radial use in the United States lags behind many countries in the rest of the world. This may be related, in part, to the lack of TRI training during fellowship for US trainees, whereas early TRI exposure outside the United States is commonplace. Additionally, no formal society guidelines defining thresholds for TRI competency currently exist. A recent European consensus statement suggests an annual minimum of 80 diagnostic and interventional radial procedures to maintain proficiency after the initial learning curve is overcome, but the threshold for what constitutes initial competency in radial technique is not specified. Recommendations from the Society for Cardiovascular Angiography and Interventions also recognize the existence of the radial learning curve and outline suggested levels of scaled competency but do not specify minimum numbers of procedures meeting these standards. The absence of threshold for initial competency in TRI is likely attributable to the lack of large-scale systematic examinations of this topic. Such a paucity may be related to the limited availability of data regarding factors influencing the learning curve and difficulty identifying and tracking operators using the radial approach for coronary angiography and PCI. Our data, which describe a national TRI learning curve, show that despite overall lower TRI volumes and predominance of postfellowship TRI training, the learning curve is similar for US versus non-US operators. Therefore, these data may facilitate the development and adoption of formal TRI training guidelines in the United States. These data also provide a national benchmark against which individual operators can track progress along their own learning curves.

Limitations
This study has important limitations. First, despite multivariable adjustment, residual confounding may be present, and we assessed operator TRI proficiency using surrogates, which may also be markers of other unmeasured factors. Second, data regarding access site crossover (an important indicator of procedure success and operator proficiency) were unavailable, and outcomes were site-reported (not adjudicated). Nevertheless, the CathPCI Registry offers an extensive database that can provide insight into contemporary cardiology practice trends. Third, our new operator definition excluded a large number of experienced operators and TRI procedures. However, we were interested in assessing changes in new operator proficiency (ie, those to whom the early learning curve for a novel technology is applicable). Additionally, our definition may have misclassified some operators as new (eg, those practicing primarily at non–National Cardiovascular Data Registry participating hospitals, including the Veterans Affairs health system, or at hospitals with intermittent National Cardiovascular Data Registry participation). The likelihood of including such operators was reduced by imposing a 6-month blanking period, and the effect of including experienced operators would have been to mask the association between TRI volume and outcomes and bias our results toward the null. Furthermore, we focused on PCI procedures, and operators might begin performing radial procedures with diagnostic angiography; as a result, the true learning curve may be steeper than what we observed. Fourth, owing to statistical limitations, low-volume operators with <15 total TRIs were excluded, and analyses were restricted to data accumulated through the 200th procedure for high-volume operators. However, we used data for the 1st through 15th TRI procedures from almost 1000 operators, and the inflection points along the learning curve in our study were well below the 200th case, making it unlikely that these restrictions significantly impacted our results. Fifth, our results may reflect that some operators with initial TRI challenges or inadequate mentorship could have dropped out and given up on the technique rather than continue to improve their TRI proficiency. Finally, these data were limited to US operators, the majority of whom learned to perform TRIs after completion of femoral PCI-based interventional cardiology fellowships. Therefore, the shape of the learning curve could be different for operators with early simultaneous exposure to both vascular approaches, yet the consistency of our results with data from Canada, where TRI training is typically acquired during fellowship, does not support this hypothesis.

Conclusions
In conclusion, adoption of TRI may be related to issues of operator proficiency and the need to overcome an assumed learning curve. With the use of data from the largest ongoing PCI registry in the United States, we demonstrate that a TRI learning curve exists, and the threshold to overcome this learning curve in current US practice is between 30 and 50 cases. In addition, we found that with growing TRI experience, operators are selecting more complex patients for TRI without sacrificing procedure success or increasing radiation exposure and contrast use. Despite overall lower
TRI volumes, our data suggest that the learning curve for the United States in comparison with previously published data from outside the United States is similar. These findings may allay the concerns of US operators over the feasibility of incorporating TRI procedures into standard practice. These data should also inform the development of formal TRI training guidelines.

Acknowledgments

We thank Erin Hanley for her editorial contributions to this manuscript. She did not receive compensation for her contributions, apart from her employment at the institution where this study was conducted. We also thank the participants of the CathPCI Registry for providing these data.

Sources of Funding

Dr Hess received support from the National Institutes of Health (5T32HL069749-09). Funding sources had no role in the design, conduct, or reporting of the study.

Disclosures

None.

References

The use of radial artery access for percutaneous coronary intervention has potential advantages over femoral access, including reduced access site bleeding, fewer vascular complications, shorter hospital length of stay, and potentially reduced mortality in patients with ST-segment elevation myocardial infarction. Despite these potential benefits, the rates of transradial percutaneous coronary intervention (TRI) remain low in the United States. Slow adoption of this approach may be related to the issues of technical proficiency and challenges with learning the technique. In this study from the National Cardiovascular Data Registry’s CathPCI Registry, data from ≈55,000 TRI procedures performed by 942 new TRI operators at 704 sites were examined. We found that as operator experience increases, higher-risk patients and more complicated cases are selected for TRI. Despite greater complexity in case selection, the rates of bleeding and vascular complications and in-hospital mortality remained low, whereas procedural success rates remained high. We further demonstrate the existence of an operator learning curve whereby procedural metrics that are markers of operator proficiency significantly improve with increasing TRI volume. Based on our data, the threshold for overcoming this learning curve is ≈30 to 50 cases, although this number will likely vary for each individual operator. Our findings suggest that the learning curve for TRI is relatively shallow with the availability of modern interventional equipment and that procedural metrics continue to improve as an operator’s TRI experience increases beyond the initial learning curve. These results should inform TRI training guidelines in the United States.
The Learning Curve for Transradial Percutaneous Coronary Intervention Among Operators in the United States: A Study From the National Cardiovascular Data Registry

Circulation. 2014;129:2277-2286; originally published online April 22, 2014; doi: 10.1161/CIRCULATIONAHA.113.006356
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2014 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/129/22/2277

Data Supplement (unedited) at:
http://circ.ahajournals.org/content/suppl/2014/04/22/CIRCULATIONAHA.113.006356.DC1

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Circulation can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Circulation is online at:
http://circ.ahajournals.org/subscriptions/
Supplemental Table 1. Proportion of PCI-treated Versus Diseased Vessels Among Patients With Multi-vessel Disease and No History of CABG Undergoing TRI Procedures According to Operator TRI Volume

<table>
<thead>
<tr>
<th>#Treated vessel / #diseased vessel</th>
<th>1-10</th>
<th>11-50</th>
<th>51-100</th>
<th>&gt;100</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(N=3,812)</td>
<td>(N=10,377)</td>
<td>(N=5,286)</td>
<td>(N=3,077)</td>
</tr>
<tr>
<td>1/2</td>
<td>2,169 (24.8)</td>
<td>5,873 (24.9)</td>
<td>3,029 (26.3)</td>
<td>1,700 (25.2)</td>
</tr>
<tr>
<td>1/3</td>
<td>690 (7.9)</td>
<td>1,758 (7.5)</td>
<td>947 (8.2)</td>
<td>544 (8.1)</td>
</tr>
<tr>
<td>2/2</td>
<td>657 (7.5)</td>
<td>1,758 (7.5)</td>
<td>855 (7.4)</td>
<td>544 (8.1)</td>
</tr>
<tr>
<td>2/3</td>
<td>215 (2.5)</td>
<td>609 (2.6)</td>
<td>330 (2.9)</td>
<td>207 (3.1)</td>
</tr>
<tr>
<td>3/3</td>
<td>26 (0.3)</td>
<td>85 (0.4)</td>
<td>51 (0.4)</td>
<td>30 (0.4)</td>
</tr>
<tr>
<td>Either #treated or #diseased missing</td>
<td>55 (0.6)</td>
<td>194 (0.8)</td>
<td>74 (0.6)</td>
<td>52 (0.8)</td>
</tr>
</tbody>
</table>
Supplemental Table 2. Evaluation of the Relationship Between Procedural Outcomes and TRI Volume Using Linear Splines

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Knot Point (k₀)</th>
<th>Slope (β₁) for Radial Volume ≤ k₀</th>
<th>Slope (β₂) for Radial Volume &gt; k₀</th>
<th>P-Value for H₀: β₁ ≠ β₂</th>
<th>AIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoroscopy time</td>
<td>30   -0.51 (-0.64, -0.39)</td>
<td>-0.04 (-0.08, 0.01)</td>
<td>&lt; 0.001</td>
<td>402287</td>
<td></td>
</tr>
<tr>
<td></td>
<td>35   -0.45 (-0.56, -0.34)</td>
<td>-0.03 (-0.07, 0.02)</td>
<td>&lt; 0.001</td>
<td>402288</td>
<td></td>
</tr>
<tr>
<td></td>
<td>40   -0.40 (-0.50, -0.31)</td>
<td>-0.01 (-0.06, 0.03)</td>
<td>&lt; 0.001</td>
<td>402287</td>
<td></td>
</tr>
<tr>
<td></td>
<td>45   -0.36 (-0.45, -0.27)</td>
<td>0.00 (-0.05, 0.05)</td>
<td>&lt; 0.001</td>
<td>402288</td>
<td></td>
</tr>
<tr>
<td></td>
<td>50   -0.33 (-0.41, -0.24)</td>
<td>0.00 (-0.05, 0.05)</td>
<td>&lt; 0.001</td>
<td>402290</td>
<td></td>
</tr>
<tr>
<td>RCS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>402104</td>
</tr>
<tr>
<td>Contrast volume</td>
<td>30   -2.27 (-3.27, -1.28)</td>
<td>-0.56 (-0.93, -0.20)</td>
<td>0.002</td>
<td>613601</td>
<td></td>
</tr>
<tr>
<td></td>
<td>35   -2.10 (-2.96, -1.24)</td>
<td>-0.50 (-0.87, -0.13)</td>
<td>0.001</td>
<td>613601</td>
<td></td>
</tr>
<tr>
<td></td>
<td>40   -2.02 (-2.78, -1.25)</td>
<td>-0.41 (-0.79, -0.03)</td>
<td>&lt; 0.001</td>
<td>613599</td>
<td></td>
</tr>
<tr>
<td></td>
<td>45   -1.91 (-2.61, -1.22)</td>
<td>-0.34 (-0.73, 0.05)</td>
<td>&lt; 0.001</td>
<td>613599</td>
<td></td>
</tr>
<tr>
<td></td>
<td>50   -1.79 (-2.43, -1.15)</td>
<td>-0.29 (-0.69, 0.11)</td>
<td>&lt; 0.001</td>
<td>613599</td>
<td></td>
</tr>
<tr>
<td>RCS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>613350</td>
</tr>
</tbody>
</table>

* Slope and 95% CI estimates are for a 10 case increase in radial case volume

AIC indicates Akaike Information Criterion; RCS, restricted cubic spline
Supplemental Figure Legends

Supplemental Figure 1. Relationship between Operator TRI Volume and Procedural Outcomes among Females

Shown here are curves depicting the unadjusted and adjusted relationships between TRI volume and fluoroscopy times (A and B, respectively); unadjusted relationships between TRI volume and contrast volume (C and D, respectively), and unadjusted and adjusted relationships between TRI volume and procedure success (E and F, respectively). Dotted lines represent 95% confidence intervals.

Supplemental Figure 2. Relationship between Operator TRI Volume and Procedural Outcomes among Patients ≥75 Years Old

Shown here are curves depicting the unadjusted and adjusted relationships between TRI volume and fluoroscopy times (A and B, respectively); unadjusted relationships between TRI volume and contrast volume (C and D, respectively), and unadjusted and adjusted relationships between TRI volume and procedure success (E and F, respectively). Dotted lines represent 95% confidence intervals.
Supplemental Figure 1

A.

B.

C.
D.

E.
F.