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MINI-FOCUS ON RADIAL ACCESS

Risk Score, Causes, and Clinical Impact of Failure of Transradial Approach for Percutaneous Coronary Interventions

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Objectives To study the causes of and to develop a risk score for failure of transradial approach (TRA) for percutaneous coronary intervention (PCI).

Background TRA-PCI failure has been reported in 5% to 10% of cases.

Methods TRA-PCI failure was categorized as primary (clinical reasons) or crossover failure. Multivariate analysis was performed to determine independent predictors of TRA-PCI failure, and an integer risk score was developed.

Results From January to June 2010, TRA-PCI was attempted in 1,609 (97.3%) consecutive patients, whereas 45 (2.7%) had primary TRA-PCI failure. Crossover TRA-PCI failure occurred in 30 (1.8%) patients. Causes of primary TRA-PCI failure included chronic radial artery occlusion (11%), previous coronary artery bypass graft (27%), and cardiogenic shock (20%). Causes for crossover TRA-PCI failure included: inadequate puncture in 17 patients (57%); radial artery spasm in 5 (17%); radial loop in 4 (13%); subclavian tortuosity in 2 (7%); and inadequate guide catheter support in 2 (7%) patients. Female sex (odds ratio [OR]: 3.2; 95% confidence interval [CI]: 1.95 to 5.26, $p < 0.0001$), previous coronary artery bypass graft (OR: 6.1; 95% CI: 3.63 to 10.05, $p < 0.0001$), and cardiogenic shock (OR: 11.2; 95% CI: 2.78 to 41.2, $p = 0.0011$) were independent predictors of TRA-PCI failure. Risk score values from 0 to 7 predicted a TRA-PCI failure rate from 2% to 80%.

Conclusions In a high-volume radial center, 2.7% of patients undergoing PCI are excluded from initial TRA on clinical grounds, whereas crossover to femoral approach is required in only 1.8% of the cases. A new simple clinical risk score is developed to predict TRA-PCI failure. (J Am Coll Cardiol Intv 2013; 6:1129–37) © 2013 by the American College of Cardiology Foundation

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Compared with transfemoral approach (TFA), transradial approach (TRA) for percutaneous coronary interventions (PCI) has been shown to significantly decrease vascular complications (1–3), promote early mobilization, shorten hospital stay (4), and lower healthcare costs (5). Although there are reports of increasing TRA-PCI adoption worldwide (6), its penetration remains highly variable, particularly in the United States (7). There are several reasons for this underutilization that might include the possibly overemphasized technical difficulties with TRA and relatively high failure and crossover rates. Existing reports on TRA-PCI failure have been confined to selected cohorts of patients in centers with low- to moderate-volume TRA practice (8). Moreover, considerable variability regarding failure rates in these reports is present, and accurate clinical risk stratification of TRA-PCI failure is consequently of clinical importance. Furthermore, the outcomes of patients with failed TRA-PCI have not been previously reported. We therefore sought to describe the incidence, mechanisms, and predictors of TRA-PCI failure in a high-volume tertiary radial center among all comers and to derive a simple clinical scoring system predictive of TRA-PCI failure. We also evaluated whether radial approach failure had an impact on clinical outcomes.

Abbreviations and Acronyms

CABG = coronary artery bypass graft

CI = confidence interval(s)

OR = odds ratio(s)

PCI = percutaneous coronary intervention(s)

TFA = transfemoral approach

TIMI = Thrombolysis In Myocardial Infarction

TRA = transradial approach

Methods

Study population. The study population consisted of all consecutive patients who underwent PCI at Québec Heart-Lung Institute from January 2010 to June 2010, irrespective of the indication. For the purpose of this study, detailed demographic, clinical, and procedural characteristics were prospectively entered into a dedicated database. Recorded data included: baseline characteristics; indication for PCI; pre-procedural laboratory tests; access site (puncture attempts, failure and success); procedural material; fluoroscopy time; contrast volume; details of coronary intervention; and, if any, need and reason for access site crossover. All major adverse clinical events covering the in-hospital phase were recorded and analyzed. The study was performed in accordance with the institutional review board guidelines, and all patients signed an informed consent prior to diagnostic angiography and PCI.

TRA-PCI technique. During the study period, operators included 6 interventional fellowship trainees (low- to intermediate-volume radial operators) as well as 12 interventional cardiologists (high-volume radial operators, with a minimum case volume of 200 PCI procedures per annum for more than 10 years).

In accordance with our institutional protocol, patients underwent assessment of radial artery patency and adequacy of dual hand blood supply using an oximetry test prior to procedure by the catheterization laboratory nurses as previously described (9). The right radial artery was the default access, and the left radial artery was used in case of previous coronary artery bypass graft (CABG) with a left internal mammary artery graft, or if the right radial artery was clinically occluded. The choice of initial and final access site for individual patients was left to the discretion of the operator.

Using a dedicated arm board, and with the patient's wrist slightly hyperextended, the right or left radial artery was cannulated after administration of 2 to 3 ml of local anesthetic, with a short, beveled, 19-gauge bare needle or 18-gauge Cathlon needle (BD Insyte, Becton Dickinson Infusion Therapy Systems Inc., Sandy, Utah), as previously described (4,10). A soft 0.035-inch straight guidewire was then advanced into the radial artery lumen, and a 10-cm 5- to 6-F nonhydrophilic introducer sheath (Terumo Medical Corporation, Elkton, Maryland) was placed into the radial artery. Following sheath insertion, an intraradial spasmolytic cocktail of 2.5 mg of verapamil was routinely administered. In case of faint radial pulse, subcutaneous 200 μg of nitroglycerin was sometimes used at the time of local anesthesia (11,12). Fluoroscopy or selective angiography of radial, brachial, or subclavian artery was only performed if difficulty was encountered in advancing the guidewire or catheters.

All patients were pre-treated with aspirin and thienopyridines (minimum loading dose of 300 mg of clopidogrel if <3 days of pre-treatment) prior to the procedure. After sheath insertion, an initial bolus of 70 IU/kg of unfractionated heparin was administered intravenously. In case of ad hoc PCI, an additional bolus of 30 IU/kg of unfractionated heparin was sometimes given prior to the first balloon inflation. Where deemed appropriate, the use of bivalirudin, or administration of glycoprotein IIb/IIIa inhibitors was at the discretion of the physician in charge of the case.

The radial sheath was removed in the operating room immediately following completion of the procedure, and hemostasis achieved by application of a locally designed adjustable plastic bracelet (ComfortClose, Benrikal Services Inc., Quebec City, Quebec, Canada), or Hemostop (Zoom Co. Médic Inc., Quebec City, Quebec, Canada). Per protocol, the bracelet was loosened every 15 min until hemostasis was achieved, usually within 2 h (13).

Definitions and study outcomes. TRA-PCI failure was defined as the inability to either start or complete the procedure via TRA. Hence, TRA-PCI failure was categorized into 2 groups: primary TRA-PCI failure when TFA access was chosen as initial access for any clinical reason (no radial puncture attempted); or crossover TRA-PCI failure, due to inability to complete the PCI procedure via TRA, requiring access site crossover to TFA. The sequence of crossover to either contralateral radial or directly to femoral was left to the

operator's discretion. If, however, after crossover to contralateral radial, the procedure was successfully completed via second TRA, then this was classified as TRA success. Radial artery spasm was defined as: 1) the inability to advance the arterial sheath or to manipulate the catheters; or 2) spasm resulting in patient discomfort requiring access site crossover.

Major adverse cardiac events were defined as death, myocardial infarction, or need for revascularization (surgical or percutaneous). Bleeding was divided into access-site– or non-access-site–related and classified according to TIMI (Thrombolysis In Myocardial Infarction) definitions (14). Vascular complications were classified as major if associated with bleeding that resulted in a drop in hemoglobin of >3 g/dl and/or the need for blood transfusion or vascular surgical repair. Local hematomas at the radial site were graded according to a specific scale as previously described (4).

Statistical analysis. Continuous variables are summarized as mean ± SD or median (interquartile range), and categorical variables as absolute numbers and percentages. Statistical comparisons were performed using Pearson test for categorical variables, whereas Kruskal-Wallis testing and analysis of variance were used for continuous variables.

To determine independent predictors of TRA-PCI failure, all 18 baseline demographic and clinical parameters in Table 1 were pre-screened by univariate logistic regression analysis. Subsequently, 8 univariate predictors of TRA-PCI failure were subjected to multivariate logistic regression analysis with stepwise, backward, and forward procedures where potential predictors of TRA-PCI failure were entered and retained in the model at $p < 0.10$. A probability value of <0.05 was considered statistically significant.

Derivation and validation of an integer risk score. Independent predictors of TRA-PCI failure according to the preceding model formed the basis of the clinical integer risk score, and we attributed a weight to each variable on the basis of the regression coefficient. Each integer amount is a rounding of the exact figure obtained from the logistic model. The area under the receiver-operating characteristics curve for the integer score was determined by calculating the C-statistic in logistic regression analyses with TRA-PCI as the dependent variable and the integer score as the independent variable. The 95% confidence limits of this C-statistic were generated by bootstrapping techniques using 1,000 replications of this model. The model's goodness of fit was evaluated using the Hosmer-Lemeshow method. The total risk score for any individual patient was the summation of the 3 independent variables present. All calculations and statistical analyses were performed using JMP (version 9.0, SAS Institute, Cary, North Carolina) and SAS (version 9.3, SAS Institute).

Table 1. Baseline Characteristics

	All Patients (N = 1,654)	TRA-PCI Success (n = 1,579)	Primary Failure (n = 45)	Crossover Failure (n = 30)	p Value
Age, yrs	66 ± 12	66 ± 12	66 ± 14	67 ± 13	0.69
Male	1,174 (71)	1,136 (72)	24 (53)	14 (47)	0.0003
Height, cm	168 ± 9	168 ± 9	166 ± 10	165 ± 9	0.047
Weight, kg	80 ± 17	80 ± 17	76 ± 16	79 ± 20	0.28
Diabetes	443 (27)	417 (26)	14 (31)	12 (40)	0.20
Hypertension	1,125 (68)	1,067 (68)	34 (76)	24 (80)	0.19
Hypercholesterolemia	1,196 (72)	1,133 (72)	40 (89)	23 (77)	0.035
Smoking history	748 (45)	714 (45)	22 (49)	12 (40)	0.75
Creatinine, µmol/l	84 (72–98)	83 (72–98)	93 (74–112)	89 (78–110)	0.040
Previous radial access	573 (35)	537 (34)	23 (51)	13 (43)	0.036
Previous PCI	460 (28)	427 (27)	22 (49)	11 (37)	0.0030
Previous CABG	218 (13)	186 (12)	23 (51)	9 (30)	<0.0001
Indication for PCI					
Stable angina	339 (21)	325 (21)	7 (16)	7 (23)	0.66
Unstable angina	501 (30)	480 (30)	11 (24)	10 (33)	0.65
NSTEMI	421 (25)	405 (26)	8 (18)	8 (27)	0.48
STEMI—primary PCI	178 (11)	170 (11)	7 (16)	1 (3)	0.25
STEMI—rescue PCI	176 (11)	168 (11)	5 (11)	3 (10)	0.99
Cardiogenic shock	13 (0.8)	8 (0.5)	4 (9)	1 (3)	<0.0001
Other	26 (2)	23 (1)	3 (7)	0 (0)	0.013

Values are mean ± SD, n (%), or median (interquartile range). Baseline characteristics of study population are categorized by access site. TRA-PCI success represents radial access. Primary and crossover failures represent femoral access.

CABG = coronary artery bypass graft; NSTEMI = non–ST-segment elevation myocardial infarction; PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction; TRA = transradial approach.

Results

A total of 1,654 patients underwent PCI during the study period and were divided into 3 groups on the basis of the success or failure of TRA-PCI (Fig. 1). In 1,609 (97.3% of total) patients, TRA-PCI was attempted and successfully completed in 1,579 (95.5%) via initial or contralateral TRA (TRA-PCI success), whereas crossover to TFA was necessary in 30 (1.8%) patients to complete the procedure (crossover TRA-PCI failure). The remaining 45 (2.7%) patients were deemed ineligible for TRA-PCI for clinical reasons and underwent PCI via initial TFA (primary TRA-PCI failure) (Fig. 1).

Baseline and clinical criteria are depicted in Table 1. Mean age of overall population was 66 ± 12 years; 71% were men; 27% were diabetic; 35% had previous radial access; 28% had previous PCI; and 13% had previous CABG. There were statistically significant differences between the 3 groups in baseline characteristics, as both the primary and crossover TRA-PCI failure groups, compared with the TRA-success group, were more likely to be women (47% and 53%, respectively, vs. 28%; p = 0.0003) and have a higher incidence of previous radial access (51% and 43% vs. 34%, p = 0.036), previous PCI (49% and 37% vs. 27%, p = 0.003), and previous CABG (51% and 30% vs. 12%, p < 0.0001). Furthermore, although procedural indications were fairly similar across groups, both primary and crossover TRA-PCI failure groups, compared with the TRA-PCI success group, had a higher incidence of cardiogenic shock at presentation (9% and 3% respectively, vs. 0.5%, p < 0.0001). The left radial approach was more commonly used as initial access in the TRA-PCI crossover failure group (23% vs. 10%, p < 0.0001) than in the TRA-PCI success group. Both TRA-PCI failure groups more often underwent left main stem and graft interventions and were more likely to receive bivalirudin as an anticoagulant (Table 2).

In both the primary and crossover TRA-PCI failure groups, fluoroscopy time was significantly longer than it was for the TRA-PCI success group (15 and 19 min, respectively, vs. 12 min, p = 0.0015). The overall angiographic success was 96.4%; however, this was significantly lower in the crossover TRA-PCI failure group than in the success group (83% vs. 97%, p = 0.0002).

Post-PCI outcomes. There was a higher incidence of major adverse cardiovascular events in both the primary and crossover TRA-PCI failure groups than in the TRA-PCI success group (13% and 3.3% vs. 2%, p < 0.0001), higher

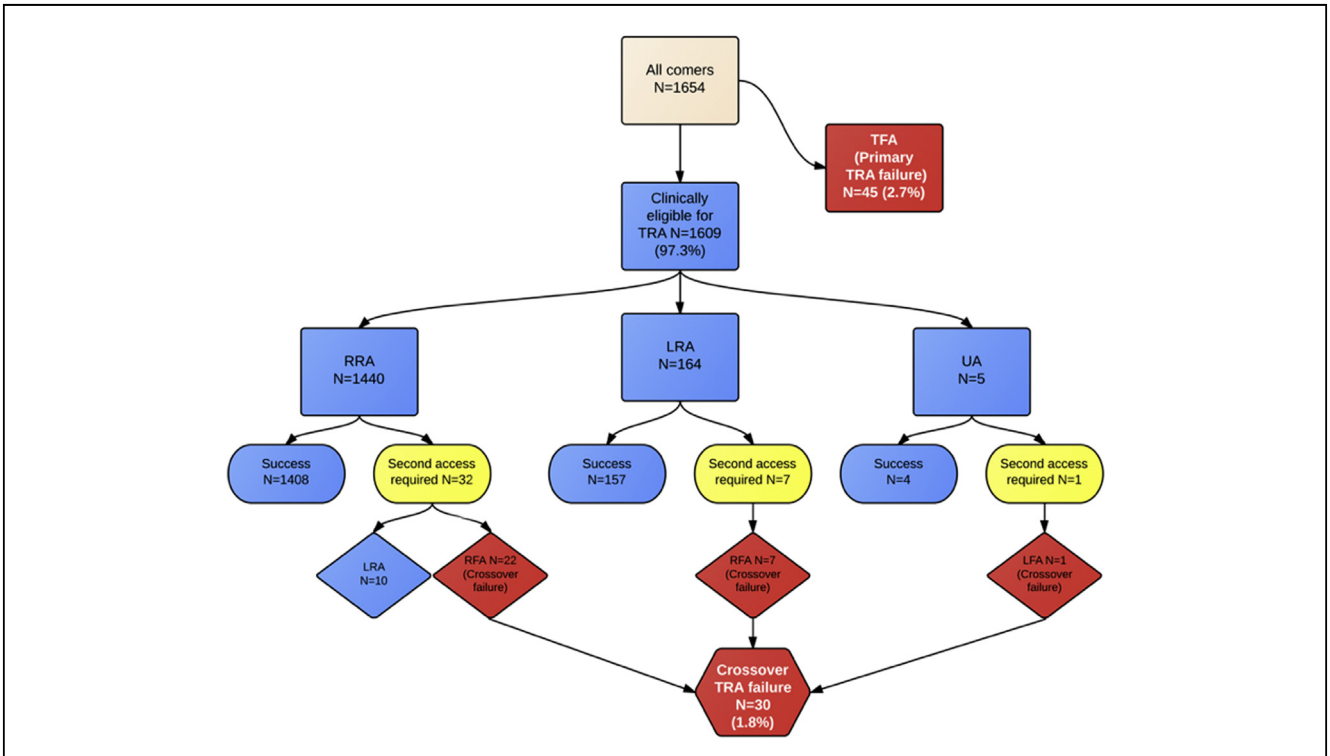

Figure 1. Access Site Flow Chart for Study Population

Flow chart showing sequence of access site selection and need for access site crossover. Primary and crossover TRA-PCI failure are shown in **red**. LFA = left femoral artery; LRA = left radial artery; PCI = percutaneous coronary intervention; RFA = right femoral artery; RRA = right radial artery; TFA = transfemoral approach; TRA = transradial approach; UA = Ulnar artery.

Table 2. Procedural Characteristics

	All Patients (N = 1,654)	TRA-PCI Success (n = 1,579)	Primary Failure (n = 45)	Crossover Failure (n = 30)	p Value
Oximetry test					<0.0001
A	50 (3)	48 (3)	1 (4)	1 (4)	
B	1,427 (91)	1,384 (91)	18 (78)	25 (93)	
C	67 (4)	67 (4)	0 (0)	0 (0)	
D	19 (1)	14 (1)	4 (17)	1 (4)	
Not performed/Allen	91	66	22	3	
First access					<0.0001
RRA	1,440 (87)	1,418 (90)	—	22 (73)	
LRA	164 (10)	157 (10)	—	7 (23)	
RUA	5 (0.3)	4 (0.3)	—	1 (3)	
FA	45 (3)	—	45 (100)	—	
Sheath					0.0002
5-F	406 (25)	393 (25)	6 (13)	7 (23)	
6-F	1,227 (74)	1,169 (74)	36 (80)	22 (73)	
7-F	15 (1)	11 (1)	3 (7)	1 (3)	
Procedure anticoagulant					
UFH	1,413 (86)	1,357 (86)	30 (67)	26 (87)	0.0013
Bivalirudin	100 (6)	89 (6)	8 (18)	3 (10)	0.0025
GPI	287 (18)	277 (18)	6 (13)	4 (13)	0.61
Treated vessel					
LMS	86 (5)	76 (5)	9 (20)	1 (3)	<0.0001
LAD	707 (43)	683 (43)	13 (29)	11 (37)	0.12
LCX	455 (28)	432 (27)	15 (33)	8 (27)	0.68
Intermediate	35 (2)	34 (2)	0 (0)	1 (3)	0.55
RCA	651 (39)	622 (39)	17 (38)	12 (40)	0.97
Graft	78 (5)	70 (4)	5 (11)	3 (10)	0.045
Vessels treated per patient					0.68
1	1,322 (80)	1,263 (80)	34 (76)	25 (83)	
2	283 (17)	271 (17)	8 (18)	4 (13)	
3	34 (2)	30 (2)	3 (7)	1 (3)	
4	3 (0.2)	3 (0.2)	0 (0)	0 (0)	
Stents per procedure	1.7 ± 1	1.7 ± 1	1.9 ± 1.5	1.7 ± 1.5	0.411
Guiding catheter per procedure	1.1 ± 0.4	1.1 ± 0.4	1.1 ± 0.5	1.3 ± 0.7	0.052
Contrast volume, ml	182 ± 72	181 ± 72	191 ± 61	201 ± 66	0.23
Fluoroscopy time, min	12 (8, 19)	12 (8, 18)	15 (9, 22)	19 (11, 33)	0.0015
Angiographic success	1,595 (96.4)	1,525 (97)	45 (100)	25 (83)	0.0002

Values are mean ± SD, n (%), or median (interquartile range). Dashes indicate that data was not observed.

FA = femoral artery; GPI = glycoprotein IIB/IIIa inhibitor; LAD = left anterior descending artery; LCX = left circumflex; LMS = left main stem; LRA = left radial artery; RRA = right radial artery; RCA = right coronary artery; RUA = right ulnar artery; UFH = unfractionated heparin; other abbreviations as in Table 1.

in-hospital mortality (13% and 3.3% vs. 1%, $p < 0.0001$), and significantly higher need for blood transfusion (6.2% and 3.3% vs. 0.3%, $p < 0.0001$). Similarly, both TRA-PCI failure groups suffered significantly more bleeding and access site vascular complications than did the TRA-PCI success group (radial access site) (9% and 10%, respectively, vs. 1.3%, $p < 0.0001$) (Table 3).

Causes and predictors of TRA-PCI failure. Common reasons for primary TRA-PCI failure (n = 45) included: radial artery occlusion (11%), previous CABG with bilateral mammary grafts or operator's preference (27%), and presentation in cardiogenic shock (20%). In contrast, crossover TRA-PCI (n = 30) was predominantly due to inadequate radial arterial puncture (57%). Other mechanisms included significant radial artery spasm in 5 patients (17%), radial loop or tortuosity in 4 (13%), subclavian tortuosity in 2 (7%), and inadequate guide catheter support in 2 (7%) (Table 4).

On multivariate analysis, female sex (odds ratio [OR]: 3.2; 95% confidence interval [CI]: 1.95 to 5.26, $p < 0.0001$), previous CABG (OR: 6.1; 95% CI: 3.63 to 10.05, $p < 0.0001$), and cardiogenic shock at presentation (OR: 11.2;

Table 3. In-Hospital Clinical Outcomes

	All Patients (N = 1,654)	TRA-PCI Success (n = 1,579)	Primary Failure (n = 45)	Crossover Failure (n = 30)	p Value
MACE	33 (2)	26 (2)	6 (13)	1 (3)	**<0.0001**
Clinical outcomes					
CABG	6 (0.4)	5 (0.3)	1 (2)	0 (0)	0.11
TVR-PCI	5 (0.3)	5 (0.3)	0 (0)	0 (0)	0.89
In-hospital death	23 (1.4)	16 (1)	6 (13)	1 (3)	**<0.0001**
Stroke	3 (0.2)	3 (0.2)	0 (0)	0 (0)	0.93
Transfusion	9 (0.5)	5 (0.3)	3 (7)	1 (3)	**<0.0001**
Any bleeding or vascular complication	28 (1.7)	21 (1.3)	4 (9)	3 (10)	**<0.0001**
Non–access site bleeding					
Genitourinary	1 (0.1)	1 (0.1)	0 (0)	0 (0)	0.98
GI bleed	1 (0.1)	1 (0.1)	0 (0)	0 (0)	0.98
Intracranial	2 (0.1)	2 (0.1)	0 (0)	0 (0)	0.95
Intraocular	0 (0)	0 (0)	0 (0)	0 (0)	—
Retroperitoneal	4 (0.2)	1 (0.1)	3 (7)	0 (0)	**<0.0001**
Access site complications					
Hematoma	14 (0.9)	9 (0.6)	2 (4)	3 (10)	**<0.0001**
Vascular surgery	0 (0)	0 (0)	0 (0)	(0)	—

Values are n (%). **Bold** values are statistically significant. Dashes indicate that calculations were not applicable. In-hospital clinical outcomes are categorized as per access site. TRA-PCI success represents radial access. Primary and crossover failure groups represent femoral site. MACE includes death, myocardial infarction, and surgical or percutaneous revascularization.

GI = gastrointestinal; MACE = major adverse cardiac events; TVR = target vessel revascularization; other abbreviations as in Table 1.

95% CI: 2.78 to 41.2, p = 0.0011) were independent predictors of TRA-PCI failure (Table 5). The C-index for our predictive model of TRA-PCI failure was 0.76 indicating good predictive ability.

Risk score of TRA-PCI failure. Based on the regression coefficients, an integer score was assigned to each of the multivariate predictors (female sex = 1, previous CABG = 2, and cardiogenic shock = 3), resulting in a possible clinical risk score of TRA-PCI failure ranging from 0 to 7 (Table 6). The incidence of observed TRA-PCI failure increased from 2% to 50% (Table 6). The predicted TRA-PCI failure according to the risk score is depicted in Figure 2. Internal validation with bootstrapping provided a C-statistic of 0.7587 (95% CI: 0.7568 to 0.7605). The model provided good calibration as indicated by the nonsignificant Hosmer-Lemeshow goodness of fit (p = 0.65).

Table 4. Causes of PCI Failure in Descending Order

Reason	n (%)
Primary failure—primary TFA, n = 45	
Cardiogenic shock	9 (20)
Previous CABG—operator preference	8 (18)
Previous TRA-PCI failure	6 (13)
Radial artery occlusion	5 (11)
Previous CABG—bilateral mammary grafts	4 (9)
Previous CABG with LIMA—LRA harvested for conduit	2 (4)
Need to preserve RA as future conduit—young patient 16 years of age	1 (2)
Fixed flexion deformity of forearm	1 (2)
Takayasu arteritis	1 (2)
Undetermined	8 (18)
Crossover failure (from TRA to TFA), n = 30	
Inadequate puncture	17 (57)
Radial spasm	5 (17)
Radial loop/tortuosity	4 (13)
Subclavian tortuosity	2 (7)
Inadequate guiding catheter support	2 (7)

LIMA = left internal mammary artery; RA = radial artery; TFA = transfemoral approach; other abbreviations as in Tables 1 and 2.

Discussion

The main findings from this study are as follows. 1) In a setting that promotes radial approach as default access site, TRA-PCI can be successfully performed in >95% of all comers, with very low primary and crossover failure rates. 2) A novel simple clinical risk score can predict TRA-PCI failure in 2% to 80% of cases. 3) Patients who undergo TFA-PCI after primary or crossover radial approach failures remain at higher risk of peri-procedural complications.

Despite the previously demonstrated advantages of TRA for PCI, widespread adoption has not yet occurred. This is probably multifactorial, due to known technical challenges and steeper learning curve of TRA practice (15) and higher failure rates requiring access site crossover that have previously been reported (1,8,16). This is also compounded by concerns on higher radiation exposure and longer procedure times (17).

Table 5. Multivariable Predictors of TRA-PCI Failure and Risk Score

Variable	Model Coefficient	Model Coefficient Rounded	Clinical Risk Score	Standard Error	Chi-Square	OR	95% CI	p Value
Female	1.1599	1	1	0.2526	21.08	3.2	1.95–5.26	<0.0001
Previous CABG	1.8018	2	2	0.2590	48.36	6.1	3.63–10.05	<0.0001
Cardiogenic shock	2.4135	3	3	0.6780	12.67	11.2	2.78–41.2	0.0011

Clinical risk score assigned to each of the 3 variables represents model coefficient (rounded to whole unit).
CI = confidence interval; OR = odds ratio; other abbreviations as in Table 1.

In a large meta-analysis of randomized trials of radial versus femoral access, Jolly et al. (1) demonstrated a significantly higher rate of access site crossover with radial access (5.9%). Compared with TFA, TRA was associated with a 3-fold increase in access site crossover (OR: 2.96; 95% CI: 2.02 to 4.35) (1). In a study of 2,100 patients undergoing TRA-PCI over a 4-year period, representing only 38% of total PCI volume, Dehghani et al. (8) showed a TRA-PCI crossover failure rate of 4.7%, where low- to intermediate-volume operators performed TRA-PCI in selected patients. In a series of 10,676 patients undergoing TRA-PCI, Burzotta et al. (16) reported an access site crossover of 4.9%. In the ACCESS (A Randomized Comparison of Percutaneous Transluminal Coronary Angioplasty by the Radial, Brachial and Femoral Approaches) study, Kiemeniej et al. (18) showed that the major cause of TRA-PCI crossover failure was the inability to obtain puncture and radial artery spasm. In the TRAP-AMI (Transradial Primary Percutaneous Coronary Intervention in Acute Myocardial Infarction) study, Gellen et al. (19) studied TRA-PCI failure in 446 patients presenting with ST-segment elevation myocardial infarction without cardiogenic shock. Primary TRA-PCI failure was 4.1% and crossover TRA-PCI failure was 4.7%. In a large randomized study comparing radial and femoral approach in primary PCI, Romagnoli et al. (20) recently showed an almost 10% of crossover in the radial group. Hence, TRA-PCI failure rates remained higher in high-risk clinical scenarios and complex procedures.

Our study represents experience from a high-volume academic tertiary center where TRA has been the default access for 20 years. In contrast to available literature, our unselected cohort included a significant proportion of patients undergoing TRA-PCI for high-risk clinical scenarios and complex procedures. Despite this, our primary and crossover TRA-PCI failure rates remained very low.

The principal cause of crossover TRA-PCI failure in the current study was the inability to gain radial arterial access (inadequate puncture), constituting 57% of total failures, often in patients with previous radial access and clinically very weak or absent radial pulse. Mechanical injury and shear stress associated with sheath insertion induces an inflammatory process that may lead to intimal hyperplasia (21), in addition to local thrombus formation (22). Intimal thickening is observed more commonly in association with repeated radial access (22). These changes could ultimately lead to chronic radial artery occlusion and limit future use of radial access. A recent international survey suggested that most radial operators do not routinely check radial artery patency following transradial catheterization (6). This also emphasizes that significant efforts should be exerted to prevent and treat acute radial artery occlusion, as a number of patients will require several procedures (23).

Furthermore, although micropuncture techniques, using smaller gauge needles and 0.021-inch wire, are used by many centers other than our own, there is currently no tangible evidence that they are associated with a higher rate of successful

Table 6. Observed Versus Predicted TRA-PCI Failure

Female	Prior CABG	Cardiogenic Shock	Score*	Patients	Observed TRA-PCI Failure	Observed %	Predicted (95% CI) %
0	0	0	0	996	15	1.5	1.8 (1.2–2.7)
1	0	0	1	433	25	5.8	5.5 (3.9–7.9)
0	1	0	2	167	19	11.4	10.0 (6.7–14.7)
0	0	1	3	7	3	42.9	17.0 (5.1–43.6)
1	1	0	4	44	11	25.0	26.1 (17.6–37)
1	0	1	5	—	—	—	39.5 (14.2–72.1)
0	1	1	6	4	1	25.0	55.4 (25.1–82.1)
1	1	1	7	2	1	50.0	79.8 (49.6–94.1)

Values are number of instances unless otherwise indicated. Dashes indicate data were not observed. *Total score represent the summation of 3 variables in any given combination (female sex, Previous CABG, cardiogenic shock). According to model coefficient, female scores as 1; previous CABG scores as 2; cardiogenic shock scores as 3. The score is the sum of these values. When more than 1 variable is observed, add 1 to the score.
Abbreviations as in Tables 1 and 5.

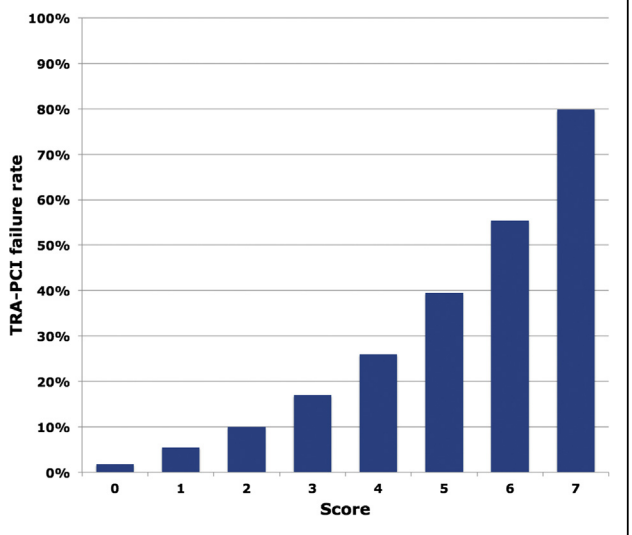

Figure 2. TRA-PCI Failure According to Clinical Risk Score

Novel risk score based on 3 independent predictors of TRA-PCI failure (female sex, previous coronary artery bypass graft, presentation in cardiogenic shock). Total score ranges from 0 to 7. Abbreviations as in Figure 1.

radial puncture. We therefore do not think our institutional practice with 18- or 19-gauge needle and 0.035-inch wire has influenced the incidence of inadequate puncture.

Our study also shows that, once radial access has been obtained, the incidence of TRA-PCI failure rate was indeed very small, mostly due to radial or subclavian tortuosity and/or radial spasm. Anatomical variations of the upper limb arterial system are relatively common and occur in 10% to 15% of cases (24). In the presence of significant tortuosity, these anomalies are a significant cause of procedural failure (25). Although some of these challenges can be overcome with special techniques (26), significant radial loops can result in severe spasm and patient discomfort, necessitating access site crossover.

In the present study, female sex, previous CABG, and cardiogenic shock at presentation were independent predictors of TRA-PCI failure. Those factors were present more often in both the primary and crossover TRA-PCI failure groups. The radial artery diameter is usually 2.5 to 3.0 mm at the level of the wrist, however, this is smaller in women (27). Moreover, female sex, diabetes, and low body mass index are independent predictors of radial artery spasm (28), which in turn may contribute to TRA-PCI failure. Similar to previous studies, we also identified previous CABG as an independent predictor of TRA-PCI failure and need to access site crossover (8). This is likely due to a combination of factors, including advanced atherosclerotic disease associated with vascular risk factors, and potential anatomical and technical challenges in these cases, such as inadequate selective graft cannulation, or poor guide catheter support for graft interventions. In addition, some operators may have a lower threshold for choice of, or crossover to, TFA for graft imaging. Therefore, the "previous CABG" risk of TRA-PCI failure may be modifiable to some extent, depending on the operator's preference and skill. We also identified cardiogenic shock as an independent predictor of TRA-PCI failure. Although TRA is possible in ~50% of patients with cardiogenic shock (29), weak or absent radial pulses in such patients represent a major challenge to obtain swift arterial access, resulting in choice of primary TFA access (primary TRA-PCI failure) (29).

Finally, we observed more ischemic and bleeding complications in the primary and crossover TRA-PCI failure groups. This finding is not unexpected as those patients were particularly at high risk. This should further emphasize that every effort and teamwork should be maximized so that the large majority of patients can undergo TRA-PCI. Conversely, using our risk score may help physicians and staff to pay particular attention to prevent and manage peri-procedural complications.

Study limitations. This is an observational study with limitations inherent to such a design. Our institution is a tertiary care academic center, where fellows and residents at various stages of training were involved in many procedures. Although there is a system in place where experienced staff take over from trainees in cases of difficult puncture or when problems arise, this information is not systematically collected. Hence, it was not possible to analyze whether operator experience played a role in failure rate. Given the retrospective nature, we were not able to ascertain specific reasons for primary TRA-PCI failure in all patients. Endpoint of total TRA-PCI failure was pool of primary and crossover failure for the purpose of this score. Although reasons and predictors of primary and crossover failure are different, they both lead to the same result: the use of TFA. Given our high-volume experience with TRA and low failure rate, our results may only be generalizable to centers in which radial approach is the default access site.

Conclusions

In a default radial center, 2.7% of all comers undergoing PCI were excluded from initial TRA on pure clinical grounds. Crossover to femoral approach was required in only 1.8% of the cases. Female sex, previous CABG, and cardiogenic shock were independent predictors of TRA-PCI failure. A novel simple clinical risk score was developed to stratify patients, and it can predict radial approach failure rates between 2% and 80% in contemporary PCI practice.

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Key Words: crossover ■ failure ■ percutaneous coronary intervention ■ radial artery ■ transradial access.