

Characterization of Operator Learning Curve for Transradial Coronary Interventions

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Background—Transradial percutaneous coronary intervention (TR-PCI) improves clinical outcomes compared to the transfemoral (TF) approach. However, inadequate training and experience has limited widespread adoption by interventional cardiologists.

Methods and Results—Clinical and procedural characteristics for TR-PCI were prospectively collected from 1999 to 2008. To identify minimum case volume for optimum clinical benefit, single-vessel TR-PCI cases were chronologically ranked and stratified into 1 to 50, 51 to 100, 101 to 150 and 151 to 300 case volume groups for operators starting the TR approach at the study institution. Cases by operators with a >300 TR-PCI case volume comprised the control group. TR-PCI failure rates, contrast use, guide usage, and fluoroscopy time were compared among groups. A total of 1672 patients underwent TR-PCI by 28 operators. TR-PCI failure occurred in 4% and was higher in the 1 to 50 case volume group compared to the 51 to 100 ($P=0.007$) and control ($P=0.01$) groups. Contrast use was greater in the 1 to 50 group (180 ± 79 mL) compared to the 151 to 300 (157 ± 75 mL, $P=0.02$) and control (168 ± 79 mL, $P=0.05$) groups. Fluoroscopy time was higher in the 1 to 50 group (15 ± 10 minutes) compared to the 101 to 150 (13 ± 10 minutes, $P=0.04$) and control (12 ± 9 minutes, $P=0.02$) groups. Reasons for TR-PCI failure included spasm (38%), subclavian tortuosity (16%), poor guide support (16%), failed access (10%), and radial loop (7%). Case volume was significantly correlated with TR-PCI failure ($\beta=-0.0076$, $P=0.0028$), and odds of failure was reduced by 32% for each 50 increments in case volume.

Conclusions—TR-PCI success depends on operator experience, and a case volume of ≥ 50 cases is required to achieve outcomes comparable to experienced operators. These findings have implications both for PCI operators looking to expand their skills and for defining standards for training. (*Circ Cardiovasc Interv.* 2011;4:336-341.)

Key Words: angioplasty ■ radial artery ■ learning

Transradial percutaneous coronary intervention (TR-PCI) has been shown to decrease vascular complications,¹⁻³ promote early ambulation,⁴ shorten hospital stay,⁵ lower healthcare costs,^{6,7} and improve clinical outcomes⁸ compared with a transfemoral (TF) approach. Despite the demonstrated benefits, TR-PCI has not gained widespread use by interventional cardiologists. A recent analysis of the National Cardiovascular Data Registry from >600 PCI sites across United States reported using TR-PCI for <2% of all procedures.¹ Similarly, low rates for TR-PCI have been reported internationally.⁹ Technical challenges and inadequate training with the potential for lower procedural success and greater contrast and radiation exposure are likely responsible for the underuse of TR-PCI. Moreover, studies that demonstrated advantages of TR-PCI enrolled patients at centers with high-volume radial operators,¹⁰⁻¹² and the results may not be generalized to predominantly TF-PCI trained and practicing operators. An

improved understanding of the TR-PCI learning curve, therefore, is important in defining prerequisite volumes for adequate training and optimization of clinical benefit, particularly in low- to intermediate-volume operators. In this study, we analyzed the learning curve for TR-PCI and investigated the relationship between procedural volume and various benchmarks of procedural success.

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Methods

Study Population

All patients who underwent TR-PCI from July 1999 to June 2008 at St Michael's hospital (Toronto, Ontario) comprised the study population. Detailed clinical and procedural information was prospectively collected in a database. The operators included interventional fellowship trainees and staff physicians with prior experience of TF

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angiography and PCI procedures who started TR procedures at the study institution with no prior TR experience or training. All nonurgent, single-vessel TR-PCIs were included in the present analysis to select a homogenous group reflecting operator early and intermediate TR experience. TR-PCI cases were chronologically ranked and stratified into first 50 and subsequent 51 to 100, 101 to 150, and 151 to 300 cases for each operator. The operators graduated from 1 case volume group to the next on the basis of total single-vessel TR-PCI volume. Consecutive single-vessel TR-PCI cases performed by operators with a >300 TR-PCI career volume comprised the control group. Multivessel, vein graft, primary, rescue, and ad hoc TR-PCI were excluded to avoid confounding. The study protocol was approved by the Research Ethics Board of St Michael's hospital.

TR-PCI Technique

For TR-PCI, the radial artery was cannulated after administration of local anesthesia using a short, beveled, 20-gauge needle. A soft, 0.025-inch straight guidewire was advanced through the needle, and a 6-F, 23-cm radial sheath (Cordis Corporation; Miami, FL) was placed. Intraarterial verapamil (2.5 mg), nitroglycerin (200 μ g), or both was administered after obtaining arterial access. PCI was performed using 6-F traditional TF guide catheters (Boston Scientific Corporation; Natick, MA; and Medtronic Inc; Maple Grove, MN). Hydrophilic radial sheaths or specially designed radial guide catheters were not used. Selective angiography of the radial, brachial, or subclavian artery was performed when difficulty was encountered in advancing the guidewire or the guide catheter.

All patients received 81 to 325 mg of aspirin and clopidogrel before PCI. Anticoagulation with unfractionated heparin or bivalirudin and administration of glycoprotein IIb/IIIa inhibitor was at the discretion of the operator. Heparin was administered at 70 U per kilogram of body weight when used in combination with a glycoprotein IIb/IIIa inhibitor or at 100 U per kilogram of body weight when used alone, with additional heparin given to maintain an activated clotting time >250 or >300 s, respectively. The radial artery sheath was removed immediately after completion of TR-PCI, and hemostasis was achieved by application of an adjustable plastic clamp over the radial artery. The clamp was gradually released over 2 to 3 hours while monitoring for access site bleeding or hematoma, ensuring adequate distal radial artery flow. The clamp was removed after satisfactory access site hemostasis had been achieved.

Definitions and Study Outcomes

TR-PCI failure was defined as an inability to complete the PCI procedure by radial approach. Vascular spasm was defined as an inability to manipulate the arterial sheath, guidewire, or guide catheter in a smooth and pain-free manner.¹³ The primary outcome was TR-PCI failure, and secondary outcomes included the number of guide catheters used, fluoroscopy time, and contrast use.

Statistical Analysis

Continuous data are summarized as mean \pm SD and binary data as absolute values and percentages. Baseline characteristics, procedural indication, and target lesions were compared using ANOVA, χ^2 test, or Fisher exact test, as appropriate. Clinical outcomes were compared among case volume groups using generalized estimating equations. To compare TR-PCI failure rates, a repeated-measures logistic regression model was used in which TR-PCI failure was the dependent variable and the case volume group the independent variable. The model assumed that all observations from a given operator were correlated, and an autoregressive correlation structure was used. For comparison of fluoroscopy times and contrast volumes, repeated-measures linear regression models were used with Tukey adjustment for multiple comparisons. Guide catheter usages were compared using repeated-measures Poisson regression model. To examine whether failure rate was a function of operator preference rather than operator skill, failure rates were compared in a subgroup of operators who contributed procedures to the 4 case volume groups. To examine whether failure rates were associated

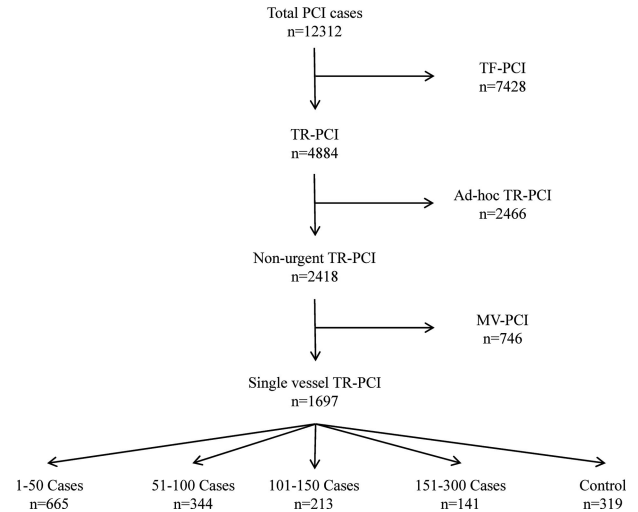


Figure 1. Patient selection for TR-PCI study cohort. MV indicates multivessel; PCI, percutaneous coronary intervention; TF, transfemoral; TR, transradial.

with operator status (trainee operator versus staff operator), a subgroup analysis was carried out by including operator status as an independent variable and an interaction term between case volume group and operator status in the repeated-measures logistic regression analysis. To determine a cutoff value for minimum volume that optimizes clinical outcome, a logistic regression model was used with TR-PCI failure as a dependent variable and operator total case volume as a continuous independent variable. In this analysis, total cases performed by each operator in each case volume group and total cases performed by the operators in the control group were included as a single value. All analyses were performed using SAS version 9.1 (SAS Institute Inc; Cary, NC) statistical software. A $P \leq 0.05$ was considered statistically significant.

Results

A total of 12 312 PCI procedures were performed during the study period (Figure 1). TR-PCI was used in 4884 (40%) patients. A total of 1,672 patients met the inclusion criteria and were chronologically ordered into 1 to 50 ($n=655$), 51 to 100 ($n=344$), 101 to 150 ($n=213$), 151 to 300 ($n=141$), and control ($n=319$) groups based on operator career TR-PCI volume. The number of operators performing TR-PCI included 22 for the 1 to 50 group, 14 for the 51 to 100 group, 7 for the 101 to 150 group, 5 for the 151 to 300 group, and 12 for the control group. Baseline and angiographic characteristics of the study population were similar across TR-PCI case volume groups (Table 1). The mean age was 62 ± 11 years, and 81% were men. The indication for PCI was stable angina in 55% of patients, unstable angina in 7%, non-ST-elevation myocardial infarction in 30%, and ST-elevation myocardial infarction in 1%.

The TR-PCI failure rates and procedural outcomes are shown in Table 2. The TR-PCI failure was reported for 69 (4%) patients in the study population and ranged from 7% in the 1 to 50 group to 3% in the 51 to 100 group, 2% in the 101 to 150 group, 3% in the 151 to 300 group, and 2% in the control group. The TR-PCI failure rate was significantly higher in the 1 to 50 group than in the 51 to 100 ($P=0.007$) and control ($P=0.01$) groups. There was no difference in the number of guide catheters used among groups. Contrast use was significantly greater in the 1 to 50 group than in the 151

Table 1. Baseline and Angiographic Characteristics

Characteristic	All Patients (n=1672)	TR-PCI Operator Experience					P
		1–50 (n=655)	51–100 (n=344)	101–150 (n=213)	151–300 (n=141)	Control (n=319)	
Age, y	62±11	63±12	62±11	62±10	61±11	63±11	0.52
Height, cm	170±9	170±9	170±10	169±9	170±9	169±9	0.78
Weight, kg	83±16	83±16	82±16	82±14	83±16	84±17	0.49
BMI, kg/m ²	29±5	29±5	28±5	29±4	29±5	29±5	0.15
Male sex	1358 (81)	547 (80)	284 (83)	172 (81)	116 (83)	260 (83)	0.96
Diabetes	368 (22)	137 (21)	79 (23)	51 (24)	29 (21)	76 (23)	0.78
Indication							
Stable angina	928 (55)	384 (59)	197 (57)	114 (53)	75 (54)	158 (50)	0.31
UA	125 (7)	56 (9)	20 (6)	10 (5)	12 (9)	27 (8)	0.23
NSTEMI	501 (30)	179 (27)	106 (31)	72 (34)	40 (28)	104 (32)	0.53
STEMI	12 (1)	3 (0.5)	4 (1)	2 (1)	1 (1)	2 (1)	0.82
Other	105 (6)	33 (5)	17 (5)	15 (7)	12 (8)	28 (9)	0.18
Target vessel*							
LAD	714 (42)	291 (44)	144 (42)	96 (45)	53 (38)	130 (41)	0.03
CX	387 (23)	132 (20)	99 (29)	43 (20)	33 (24)	80 (25)	
RCA	559 (33)	226 (34)	99 (29)	72 (34)	54 (39)	108 (34)	
LM	6 (0.3)	3 (0.5)	0 (0)	2 (1)	0 (0)	1 (0.3)	
GPA	1219 (73)	459 (70)	248 (72)	164 (77)	114 (81)	234 (73)	0.34
Bivalirudin	86 (5)	36 (5)	32 (9)	6 (3)	0	12 (4)	0.09
Stents per patient	1.3±1	1.3±1	1.4±1	1.4±1	1.4±1	1.3±1	0.59

Data are presented as mean±SD or n (%). BMI indicates body mass index; CX, left circumflex coronary artery; GPA, glycoprotein IIb/IIIa platelet receptor antagonist; LAD, left anterior descending coronary artery; LM, left main coronary artery; NSTEMI, non-ST-elevation myocardial infarction; RCA, right coronary artery; STEMI, ST-elevation myocardial infarction; TR-PCI, transradial percutaneous coronary intervention; UA, unstable angina.

*Analyzed by Fisher exact test using a 4×5 contingency table.

to 300 (180±79 versus 157±75 mL, $P=0.02$) and control (180±79 versus 168±79 mL, $P=0.05$) groups. Fluoroscopy time decreased with increasing volumes and was significantly higher in the 1 to 50 group than in the 101 to 150 (15±10 versus 13±10 minutes, $P=0.04$) and control (15±10 versus 12±9 minutes, $P=0.02$) groups.

The reasons for TR-PCI failure included radial artery spasm in 38% of patients, subclavian tortuosity in 16%, poor

guide catheter support in 16%, failure to obtain arterial access in 10%, and radial artery loop in 7% (Table 3). On logistic regression analysis, case volume was significantly correlated with TR-PCI failure ($\beta=-0.0076$, $P=0.0028$). The odds of failure declined substantially up to 50 cases, and further decline after 100 cases was small. Figure 2A shows the relationship between TR-PCI volume and failure rates, Figure 2B shows the odds ratios for TR-PCI failure. Odds of failure

Table 2. Procedural Outcomes

	TR-PCI Operator Experience				
	1–50 (n=655)	51–100 (n=344)	101–150 (n=213)	151–300 (n=141)	Control (n=319)
TR-PCI failure*	43 (7)	10 (3)	5 (2)	5 (3)	6 (2)
No. guides†	1.4±1	1.4±1	1.3±1	1.3±1	1.3±1
Contrast volume, mL‡	180±79	174±79	170±79	157±75	168±79
Fluoroscopy time, min§	15±10	14±10	13±10	11±8	12±9

All values are mean±SD or n (%). Abbreviation as in Table 1.

*Analyzed by repeated-measures logistic regression model ($P=0.007$ [1–50 vs 51–100], $P=0.01$ [1–50 vs control]).

†Analyzed by Poisson regression model ($P=0.90$).

‡Analyzed by repeated-measures linear regression model on log-transformed contrast volume with Tukey adjustment for multiple comparisons ($P=0.007$ [overall], $P=0.02$ [1–50 vs 151–300], $P=0.05$ [1–50 vs control]).

§Analyzed by repeated-measures linear regression model on log-transformed fluoroscopy time with Tukey adjustment for multiple comparisons ($P=0.003$ [overall], $P=0.04$ [1–50 vs 101–150], $P=0.02$ [1–50 vs control]).

Table 3. Causes of TR-PCI Failure

Cause	Total (n=69)	TR-PCI Operator Experience				Control (n=6)
		1–50 (n=43)	51–100 (n=10)	101–150 (n=5)	151–300 (n=5)	
Radial artery spasm	26 (38)	15 (35)	5 (50)	1 (20)	1 (20)	4 (66)
Subclavian tortuosity	11 (16)	7 (16)	...	2 (40)	1 (20)	1 (17)
Inadequate guide support	11 (16)	8 (18)	1 (10)	2 (40)
Inadequate arterial puncture	7 (10)	6 (14)	1 (10)
Radial artery loop	5 (7)	4 (9)	1 (10)
Need for contralateral injection	2 (3)	...	1 (10)	...	1 (20)	...
Inadequate guide engagement	2 (3)	1 (2)	1 (10)
Radial artery dissection	1 (1)	1 (2)
Radial artery perforation	1 (1)	1 (20)	...
Radial artery thrombus	1 (1)	1 (20)	...
Radial artery stenosis	1 (1)	1 (2)
Unknown	1 (1)	1 (17)

Data are presented as n (%). Abbreviation as in Table 1.

decreased by 8% for 10 and 32% for 50 increments in TR-PCI volume per operator. Analysis for operator status (trainee operator versus staff operator) and TR-PCI failure rate showed that failure rate was significantly associated with case volume ($P=0.004$) but not associated with operator status. In addition, there was no significant interaction between case volume group and operator status. In the subgroup of operators that contributed procedures to all 4 case volume groups, a similar pattern of lower failure rates was observed with increasing case volumes, and TR-PCI failure rate was significantly high for the 1 to 50 versus the 51 to 100 case volume group ($P=0.004$).

Discussion

To our knowledge, this study is the largest to analyze the TR-PCI learning curve and examine the relationship between TR-PCI volume and failure rates. The main findings are that the TR-PCI learning curve is steep, with no significant difference in failure rate after 50 TR-PCI cases compared to that of experienced operators. The fluoroscopy time and contrast volume usage decreased with higher procedural volumes but showed a modest absolute change after 50 cases. Inadequate arterial puncture and radial artery spasm accounted for most failures during the first 50 cases. These findings suggest that benefits offered by TR-PCI can be realized by low- to intermediate-volume operators without added procedural complexity or risk.

The Case for TR-PCI

There has been an increased focus to reduce major bleeding in cardiac patients because of its impact on morbidity and mortality.^{14–17} A significant number majority of bleeding episodes occurring in these patients are related to vascular access for invasive cardiac procedures with concomitant antiplatelet and anticoagulant therapy.^{14,18} Furthermore, a reduction in major bleeding in high-risk patients has been shown to decrease mortality and adverse clinical events.^{15,17} The TR approach for coronary angiography and PCI reduces

bleeding and vascular complications compared to the TF approach.¹⁹ In addition to improving patient outcomes, TR-PCI offers the potential for early patient ambulation,⁴ same-day discharge,^{5,20} reduced healthcare resource utilization,^{6,7} and greater patient satisfaction.^{5,19}

Although, the application of TR-PCI has significantly increased since first reported by Kiemeneij and Laarman,²¹ overall use remains <2% in the United States¹ and accounts for <12% of total PCI volume internationally.⁹ The major barrier to greater adoption is perceived technical challenges resulting in low procedural success, high use of contrast media, and increased radiation exposure, particularly in low- to intermediate-volume operators. In addition, lack of adequate TR-PCI experience during interventional cardiology training and limited exposure during radial courses contributes to subdued enthusiasm for changing practice patterns.

The TR-PCI Learning Curve

Few studies have examined the learning curve for diagnostic coronary angiography from the TR approach. However, these studies are limited in scope for methodological reasons. Louvard et al²² examined the TR angiography learning curve for 1 operator in 800 patients. Only 3 volume cohorts (<50, 50 to 500, and >500) were defined, with failure rates decreasing from 10% to 4% to 1%, respectively. Similarly, Spaulding et al²³ described the learning curve for left-side radial angiography for 1 operator in 415 patients. A failure rate of 14% was reported for the first 80 cases compared to 2% in the last 100 cases. Salgado Fernandez et al²⁴ also compared the procedural success and procedure and fluoroscopy time between the first 200 and subsequent 326 TR angiographic studies at their institution and reported better outcomes with greater experience, but no information was provided for number of operators or their TR experience. Apart from the 3 studies of learning curve for TR angiography, 1 report investigated the learning curve in patients undergoing TR-PCI¹³; however, the study included 1 operator and 27 patients.

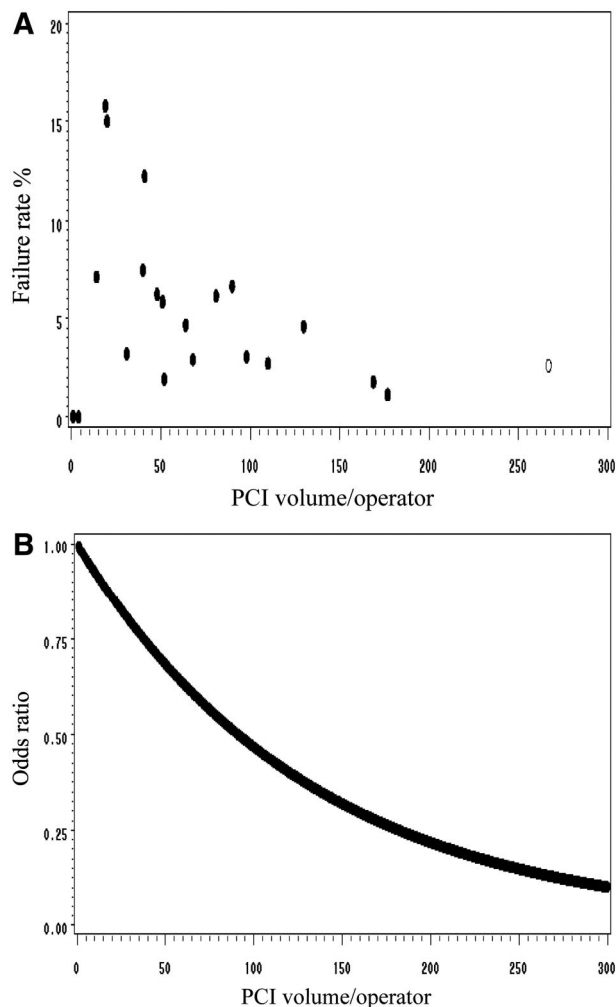


Figure 2. Relationship between TR-PCI volume and failure rate. **A**, Data for individual operators are shown. Solid circles represent individual TR-PCI operators for 4 experience groups and the open circle represents the control group shown as a reference. Case volume was defined as total cases performed by individual operators in the 4 experience groups and total cases performed by all operators in the control group. **B**, Data illustrated as odds ratios of failure to total TR-PCI volume. The results of logistic regression analysis showed that the relative odds of TR-PCI failure decline substantially up to 50 cases, and further decline after 100 cases is small. Abbreviations as in Figure 1.

Compared with these previous reports on the TR learning curve, which predominantly focused on diagnostic angiography, the present study examined a large number of TR-PCI procedures performed by several operators with a known PCI volume and a wide range of experience. The relationship between TR-PCI volume and failure demonstrated high failure rate with wide interoperator variability for a 1 to 50 TR-PCI case volume and a consistent reduction in failure rate with higher TR-PCI volumes (Figure 2A). Furthermore, the odds of TR-PCI failure decreased by 8% for 10 and 32% for 50 increments in TR-PCI volume per operator (Figure 2B).

The present findings have important implications for contemporary PCI practice. First, the identification of a minimum volume for optimal clinical outcome can be a guide for TF operators to incorporate a higher proportion of TR-PCIs in

their practice and for allowing training courses and certification organizations to define minimum standards for proficiency. Second, interventional cardiology training programs could ensure a minimum number of TR-PCI procedures as future interventional cardiologist will benefit from proficiency in both TF and TR-PCI. Contrary to common practice of using TR-PCI when TF-PCI is not feasible, appropriate patient selection during the learning curve can improve outcomes in all patients, including those at high risk of bleeding and vascular complications. In addition, the most common cause of TR-PCI failure was related to the arterial access site, and meticulous attention for obtaining successful arterial access and prevention of radial artery spasm is critical for flattening the TR-PCI learning curve.

In the recently reported RIVAL (Radial Versus Femoral Access for Coronary Angiography and Intervention in Patients with Acute Coronary Syndromes) trial,¹⁹ all study operators had performed >50 radial procedures, and clinical outcomes were reported according to the participating center's annual TR-PCI volume. A significant reduction in major vascular complications was observed for both the highest and the lowest TR-PCI center volume tertiles compared to the TF approach. However, a consistent reduction in vascular complications or access site crossover rate was not seen with higher TR-PCI center volume tertiles, a finding consistent with our results and suggesting limited incremental benefit with increasing case volume for experienced TR-PCI operators.

Study Limitations

There are important limitations of our analysis. We describe the learning curve for single-vessel TR-PCI. A different learning curve may exist for complex coronary interventions, including multivessel, vein graft, primary, and ad hoc PCI, and for patients with comorbidities such as obesity and old age. In addition, TR-PCI case selection was at the discretion of operators; thus, a selection bias cannot be excluded. However, appropriate case selection is an important part of the learning curve for any new skill or technique and essential for limiting complications.

Conclusions

TR-PCI success depends on the operator's experience, and a case volume of ≥ 50 cases is required to achieve outcomes comparable to experienced operators. The present findings have implications both for PCI operators looking to expand their skills and for defining standards for training.

Disclosures

None.

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CLINICAL PERSPECTIVE

Despite the demonstrated benefits, transradial percutaneous coronary intervention (PCI) has not achieved widespread use. Technical challenges and inadequate training are likely reasons. In the present study, we analyzed the learning curve for transradial PCI and investigated the relationship between case volume and various benchmarks of procedural success. The results showed that transradial PCI success depends on the operator's experience, with a steep learning curve. A case volume of ≥ 50 cases is adequate to optimize clinical outcomes, with no difference in procedural success rates compared to that of experienced operators. These findings suggest that benefits offered by transradial PCI can be realized by low- to intermediate-volume operators without added procedural complexity or risk and have important implications both for PCI operators looking to expand their skills and for defining standards for training.

Characterization of Operator Learning Curve for Transradial Coronary Interventions

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