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ACCESS

Switching from Femoral to Routine Radial Access Site for ST-Elevation Myocardial Infarction: A Single Center Experience

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***Objectives**: This study sought to describe the change of first choice access site from transfemoral (TF) to transradial (TR) in primary percutaneous coronary intervention (pPCI) in a single center.*
***Background**: TR-pPCI, when performed by experienced operators, can reduce bleeding events and improve clinical outcome. However, little is known about the learning curve of TR-pPCI and the results obtained by less experienced operators.*
***Methods**: Time to reperfusion, contrast and radiation doses, and 30-day clinical events were evaluated. The relationship between operator experience and procedural results was assessed.*
***Results**: During 6.5 years, 1,045 patients with STEMI underwent pPCI. The rate of TR-pPCI increased gradually from about 40% to 90% and remained stable thereafter. The crossover from TR to TFpPCI occurred in 4.6% of patients and was not related to the operator experience. Patients selected for TR-pPCI had a lower risk profile and lower incidence of 30-day mortality and bleeding events. Time to reperfusion, contrast volume, fluoroscopy time, and angiographic success was not significantly different between the 2 vascular approaches, nor was it associated to the operator experience. At roughly 200 PCIs as operator experience, a slight adjusted reduction in the time form first coronary angiogram to balloon was detected with both vascular approaches.*
***Conclusions**: A progressive transition from TF to TR-pPCI could be implemented over a 4-year period without increasing overall treatment delay. The impact of operator experience on procedural results appeared to be modest and it did not differ in the study access groups.* (J Interven Cardiol 2014;27:591–599)

Introduction

Primary percutaneous coronary intervention (pPCI) is the treatment of choice for reducing mortality and morbidity of ST-elevation myocardial infarction (STEMI).[1,2] Aggressive antithrombotic and antiplatelet regimens, warranted to reduce adverse ischemic events, can increase bleeding events, which in turn may limit the benefit of pPCI and eventually increase mortality.[3,4] Two randomized clinical trials[5–7] showed that transradial (TR)-pPCI may be associated with a reduction in bleeding and mortality when compared with transfemoral (TF) access. However, these results were obtained in high-volume radial centers by highly experienced radial operators. The outcome of TR-pPCI performed by less experienced operators is not well known, and the operator minimum experience to proficiently perform TR-pPCI has not been determined. TR-pPCI performed by less experienced operators could be associated with an increase in radiation exposure, contrast dose and procedural time, the latter being particularly important in patients with STEMI. Furthermore, the feasibility rate of TR-pPCI in an unselected STEMI population has not been established. Aim of this study is to describe the process of changing from a first choice TF to TR approach in all-comers STEMI patients undergoing pPCI. Procedural results including door-to-balloon time, contrast and radiation doses, and 30-day ischemic and bleeding events were evaluated. The relationship between

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operator experience and procedural outcome was also assessed.

Methods

Patients and Treatment. All consecutive STEMI patients admitted to our center between January 2006 and June 2012 were included in the study. Informed consent for the invasive procedure and for use of clinical data for scientific purpose was obtained in all conscious patients. The study complies with the principles outlined in the Declaration of Helsinki and with the local legal requirements. Clinical and procedural data were prospectively entered in a dedicated database in order to monitor the process of changing the preferred vascular access. Patients received aspirin 250 mg, unfractionated heparin 100 UI/kg, clopidogrel 600 mg. Abciximab use was left to operator's preference. Aspirin100 mg/day was administered indefinitely and clopidogrel 75 mg/day for at least 1 month. At the beginning of the study period, all operators agreed to consider TR approach as the first choice for pPCI, except in case of hemodialysis or bilateral mammary artery grafts, where TF approach was still preferred. Less experienced operators were also advised to avoid TR-pPCI in case of a weak pulse or a small radial artery, especially during off-hours or whenever tutoring by more experienced operator was not available. Patients were categorized according to the first attempted arterial access. The radial artery was cannulated with a 6 French 25 cm long hydrophilic introducer sheath. For both vascular approaches, 6 French diagnostic and guiding catheters were used. The clinical and procedural variables, including the time of symptom onset, arrival to hospital and catheterization laboratory door, first coronary angiogram, and first balloon inflation or thrombectomy, were prospectively collected. Thirty-day clinical information was obtained by office visit.

Operator Experience. The access-related operator experience was defined as the progressive number of PCIs already performed by the same vascular access, in any clinical condition, at the time of the index pPCI. The access-related operator experience was counted separately for both accesses and updated throughout the study. At January 2006, only 1 operator had an experience of more than 400 TR PCIs, but he did mainly teaching and supervision and performed only a minority of pPCIs. The other 2 operators, as well as other 2 operators joining the group later on, started with a TR experience of less than 50 cases. The initial TF experience for all operators was of at least 130 PCIs.

Definitions. STEMI was defined as chest pain lasting at least 20 min associated with ST-segment elevation $\geq$1 mm in 2 or more adjacent leads or new onset left bundle branch block. Off-hours presentation was defined as hospital admission from 8 P.M. to 7.59 A.M. or during weekends or public holidays.

Bleeding events were assigned according to the Thrombolysis In Myocardial Infarction (TIMI) bleeding classification.[8] Briefly, TIMI major bleeding was defined as fatal or intracranial bleeding or a $\geq$5 g/dL decrease in hemoglobin concentration, TIMI minor bleeding was defined as clinically overt blood loss and decrease in hemoglobin of 3 to $<$5 g/dL, and TIMI minimal bleeding was defined as any hemorrhage that did not meet the criteria above.

Statistical Analysis. Quantitative variables are presented as mean $\pm$ SD or median and interquartile range (IQR) and compared with the median tests. Categorical variables are presented as numbers and percentages and compared with chi-square or Fisher exact tests as appropriate. Multiple logistic regression was applied to hemoglobin drop (cut-point 3 g/dL), while adjusting for confounding factors including gender, age, operator, year, Global Registry of Acute Coronary Events (GRACE) risk score,[9] off-hours intervention, abiciximab treatment, intraaortic balloon use, and comorbidities. Statistical significance of each logistic term was obtained using the likelihood ratio test. The combined effect of access-related operator experience and vascular access on the procedural outcomes was assessed through multiple linear regression. Only operator experience between 100 and 550 cases, where both vascular accesses were represented, was considered for analysis. Given the right skewed distributions of all study outcomes, they were analyzed as log-transformed variables. Statistical significance of each regression term was assessed using the F test. In all statistical testing, a 2-sided P-value $<$ 0.05 was considered significant. All statistical analyses were carried out with STATA (version 11.0, STATA Corporation, College Station, TX).

Results

Patients and Procedures. During the study period, 1,095 consecutive patients with STEMI presented to our center within 12 hours from the symptom onset.

Of those, 4 patients (0.4%) died before the angiogram and 33 (3.0%) did not receive acute reperfusion. The remaining 1,045 patients (95.4%), who underwent emergency coronary angiogram with the intent to perform pPCI, were included in the analysis.

Overall, 710 patients (68%) underwent TR-pPCI and 335 patients (32%) TF-pPCI. The rate of TR approach increased from 40% in 2006 up to roughly 90% in 2010 and it remained stable thereafter. Although the initial proportion of TR-pPCI differed among the 4 operators, they all reached a 90% rate of TR-pPCI (Fig. 1). The baseline patients' characteristics and the angiographic and procedural variables are outlined in Tables 1 and 2. Patients selected for TF-pPCI presented a higher risk profile including a significantly higher prevalence of diabetes, prior coronary surgery, hypotension, pre-hospital cardiac arrest, Killip class II–IV, renal failure, and higher GRACE risk score. In addition, TF-pPCI patients were more likely to be females, lower in weight and height, and to present off-hours. Vascular access crossover occurred in 31 TR-pPCI patients (4.4%). The reason was failed radial puncture (9 cases), radial loop, spasm or other radial abnormalities (11 cases), tortuosity or occlusion of the brachiocephalic trunk (6 cases), and suboptimal guiding catheter back-up (5 cases). Crossover was associated with a longer door-to-balloon time (median 75 min, IQR 61–93 min vs. median 43 min, IQR 28–72 min, $P < 0.001$). The lower use of abciximab observed in the TR-pPCI patients is explained by the much higher rate of TR approach in the later part of the study period, when glycoprotein IIb/IIIa inhibitors were less employed. Consistently with the higher Killip class, patients selected for TF-pPCI more frequently underwent intraaortic balloon placement and presented a higher peak of troponin T and a longer hospital stay. Contrast volume, fluoroscopy time, door-to-balloon time, catheterization laboratory entrance-to-balloon time, first coronary angiogram-to-balloon time, and angiographic success rate was not significantly different between the 2 vascular approaches.

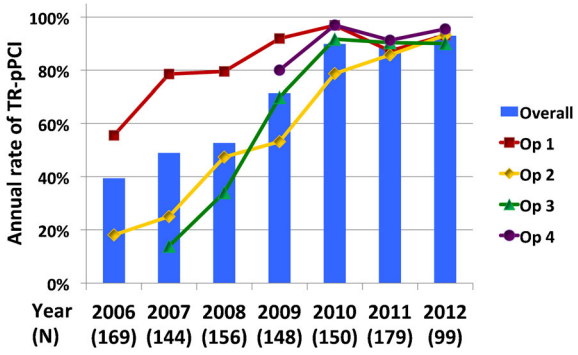

Figure 1. Temporal trend in access site for pPCI. Lines indicate the annual rate of TR-pPCI for the individual operators. Bars indicate the overall annual rate of TR-pPCI. Only the first semester of year 2012 was considered. Numbers in parenthesis are the treated patients in the corresponding period. Op, operator; pPCI, primary percutaneous coronary intervention; TR, transradial.

Thirty-Day Results. Cardiovascular adverse and bleeding events at 30 days are outlined in Table 3. Mortality was significantly higher in patients selected for TF-pPCI. TR-pPCI was associated with a lower occurrence of access-site TIMI major bleed and overall TIMI minor bleed, a lower blood transfusion rate, and lower incidence of hemoglobin drop $\geq$3 g/dL. TF-pPCI was independently associated with a higher rate of hemoglobin drop $\geq$3 g/dL (odds ratio: 5.60, 95% confidence interval: 2.75–11.20, $P < 0.001$).

Analysis by Tertiles of GRACE Risk Score. To improve the comparability of TR and TR approach, the patients were stratified by tertiles of GRACE risk score. When comparing TR and TF approach in patients with similar GRACE risk score, all baseline characteristics, except height, weight, and abciximab use, showed no longer a significant difference. Likewise, several procedural results, such as times of treatment, fluoroscopy time and contrast volume, were similar or showed nonsignificant differences between TR and TF patients. Conversely, in TF patients, the incidence of hemoglobin drop $\geq$3 g/L remained about double across all tertiles of GRACE risk score (Table 4).

Temporal Trend in TR-pPCI and Associated Factors. The uptake of TR-pPCI increased through years 2006–2009 (Phase 1, 617 patients, TR rate 52%), followed by a plateau throughout years 2010–2012 (Phase 2, 428 patients, TR rate 90%). The covariates associated to access site selection during these 2 distinct phases are displayed in Figure 2. The increase of TR-pPCI from Phase 1 to Phase 2 was consistent across all subgroups, but more evident in patients with prior coronary bypass surgery, systolic blood pressure $\leq$100 mmHg, female gender, and off-hours presentation. Likewise, the increase in TR-pPCI rate was associated to the access-related operator experience (Fig. 3), although different trends among the operators are noticeable. Operator 3, who joined the team in 2007, presented a steeper relation between experience and TR-pPCI rate as compared with Operators 1 and 2.

Table 1. Baseline and Presenting Characteristics

Characteristic	TR-pPCI (n = 710)	TF-pPCI (n = 335)	P Value
Age	66.4 ± 13.1	68.0 ± 12.4	0.158
Age ≥ 80	122 (17.2)	71 (21.2)	0.119
Females	173 (24.4)	111 (33.1)	0.003
Height (cm)	169.1 ± 8.2	167.2 ± 7.7	0.002
Weight (kg)	76.6 ± 14.4	73.7 ± 11.9	<0.001
Body surface area (m^2)	1.87 ± 0.19	1.82 ± 0.17	0.004
Body mass index (kg/m^2)	26.7 ± 4.1	26.3 ± 3.7	0.609
Hypertension	411 (57.9)	206 (61.5)	0.177
Current smokers	291 (41.0)	130 (38.8)	0.660
Diabetes mellitus	160 (22.5)	95 (28.4)	0.042
Prior myocardial infarction	68 (9.6)	41 (12.2)	0.183
Prior percutaneous coronary intervention	56 (7.9)	26 (7.8)	0.965
Prior coronary surgery	10 (1.4)	14 (4.2)	0.005
Prior stroke	22 (3.1)	16 (4.8)	0.099
Off-hours presentation	383 (53.9)	204 (60.9)	0.035
Systolic blood pressure (mmHg)	142 ± 30.0	134.5 ± 34.9	<0.001
Heart rate (bpm)	75.9 ± 18.1	75.8 ± 22.4	0.083
Hemoglobin (g/dL)	13.9 ± 1.81	13.7 ± 1.84	0.428
Glomerular filtration rate (mL/min)*	85.1 ± 35.3	76.3 ± 32.8	<0.001
Pre-hospital cardiac arrest	12 (1.69)	18 (5.37)	0.001
Killip class II–IV	30 (4.2)	36 (10.8)	<0.001
Anterior STEMI	275 (38.7)	136 (40.6)	0.675
GRACE risk score ≥ 126	158 (22.3)	107 (31.9)	0.001

Values are mean ± SD or n (%). GRACE, Global Registry of Acute Coronary Events; pPCI, primary percutaneous coronary intervention; STEMI, ST elevation myocardial infarction; TF, transfemoral; TR, transradial. *According to Cockroft-Gault formula.

Table 2. Angiographic and Procedural Variables

Variable	TR-pPCI (n = 710)	TF-pPCI (n = 335)	P Value
Crossover to other access	31 (4.4)	0 (0.0)	<0.001
Multivessel disease	278 (39.2)	145 (43.3)	0.434
Use of abciximab	517 (72.8)	289 (86.3)	<0.001
pPCI performed	679 (95.6)	315 (94.0)	0.261
Angiographic success*,†	654 (96.3)	296 (94.0)	0.245
Stent*	603 (88.8)	272 (86.3)	0.267
Intraaortic balloon pump	24 (3.4)	29 (8.7)	<0.001
Contrast volume (mL)	159.6 ± 59.0	171.6 ± 79.5	0.121
Fluoroscopy time (min)	11.5 [8.1–18.0]	10.9 [7.0–18.0]	0.411
Door-to-balloon time (min)*	45 [29–74]	42 [25–76.5]	0.321
Catheterization laboratory entrance-to-balloon time (min)*	29 [22–38]	27 [20–37]	0.178
First coronary injection-to-balloon time (min)*	8 [5–13]	9 [5–14]	0.269
Peak troponin T (ng/mL)	3.96 [1.56–7.62]	4.95 [2.41–8.83]	0.008
Pre-discharge ejection fraction (%)	52.1 ± 9.8	51.3 ± 10.5	0.432
Hospital stay ≥6 days	119 (16.8)	81 (24.2)	0.004

Values are mean ± SD or median [interquartile range] or n (%). Abbreviations as in Table 1. *Among patients who had pPCI. †Angiographic success = final thrombolysis in myocardial infarction flow grade 2 or 3 and residual stenosis <50%.

Table 3. Cardiovascular Adverse and Bleeding Events at 30 Days

Variable	TR-pPCI (n = 706)*	TF-pPCI (n = 335)	P Value
Death	38 (5.4)	40 (11.9)	<0.001
Recurrent myocardial infarction	4 (0.6)	3 (0.9)	0.539
Urgent coronary surgery	4 (0.6)	2 (0.6)	0.946
Target vessel revascularization	6 (0.9)	3 (0.9)	0.934
Ischemic stroke	3 (0.4)	3 (0.9)	0.345
TIMI major bleed	8 (1.1)	13 (3.9)	0.003
Access site related	2 (0.3)	6 (1.8)	0.004
Intracranial	2 (0.3)	1 (0.3)	0.962
Other nonaccess site related	4 (0.6)	6 (1.8)	0.085
TIMI minor bleed	18 (2.6)	20 (6.0)	0.006
Any blood transfusion	13 (1.8)	17 (5.1)	0.003
Need for vascular surgery	0 (0.0)	2 (0.6)	0.103
Hemoglobin drop ≥3 g/dL	56 (7.9)	60 (17.9)	<0.001
Death, MI, stroke or TIMI major bleed	48 (6.8)	53 (15.8)	<0.001

Values are n (%). TIMI, thrombolysis in myocardial infarction; other abbreviations as in Table 1. *Four patients lost to follow-up were excluded.

Table 4. Selected Cardiovascular Adverse and Bleeding Events at 30 Days by Tertiles of GRACE Risk Score

	Lower Tertile (GRACE Risk Score 51–93) N = 332			Mid Tertile (GRACE Risk Score 94–117) N = 331			Upper Tertile (GRACE Risk Score 118–210) N = 332		
	TR-pPCI (N = 233)	TF-pPCI (N = 96)	P Value	TR-pPCI (N = 236)	TF-pPCI (N = 95)	P Value	TR-pPCI (N = 208)	TF-pPCI (N = 124)	P Value
Hemoglobin drop ≥ 3 g/dL	12 (5.1)	10 (10.4)	0.082	15 (6.4)	16 (16.8)	0.003	27 (13.0)	30 (24.2)	0.009
Death, MI, Stroke or TIMI major bleed	5 (2.1)	1 (1.0)	0.676	10 (4.2)	7 (7.4)	0.273	26 (12.5)	30 (24.2)	0.006

Values are n (%). Abbreviations as in Tables 1–3.

Operator 4 started in 2009 already with a TR-pPCI rate above 80%. However, in patients with Killip class II–IV, TR-pPCI rate did not exceed 60% even in Phase 2 (Fig. 2).

Learning Curve of TR and TF Approach. No significant association was found between access-related experience (number of prior PCI's with consistent access site) and contrast volume, fluoroscopy time, door-to-balloon time or catheterization laboratory-to-balloon time. However, a significant adjusted relationship between access-related experience and time from first coronary angiogram to balloon inflation was detected (Fig. 4). The curves appeared to flatten at an operator experience of about 200 PCIs. Notably, the curves for TR or TF showed a comparable slope, possibly suggesting the need for a similar learning process for both access sites. The weight of the operator-related variability, as percentage of the global variability, was relatively small (3.8% for first angiogram-to-balloon time, 14.4% for contrast volume, and 13.7% for fluoroscopy time).

Discussion

The main findings of this observational study can be outlined as follows:

1. A progressive transition from first-choice TF to TR-approach in all-comers STEMI patients could be successfully implemented, reaching a plateau of TR-pPCI rate of about 90%.
2. This process required about 4 years to be implemented.
3. The increased use of TR approach was not associated with an increase in door-to-balloon time, contrast volume, or fluoroscopy time, and the crossover rate remained acceptable.

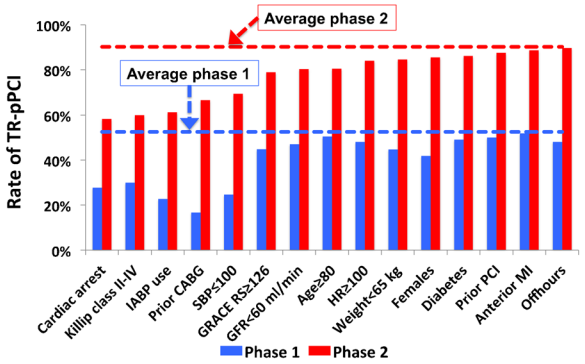

Figure 2. Rate of TR-pPCI in selected subgroups in Phase 1 (years 2006–2009) and Phase 2 (years 2010–2012). The horizontal lines indicate the average rate of TR-pPCI. In Phase 1 this rate was 52.5% while in Phase 2 this rate increased to 90%. Bars indicate the rate of TR-pPCI in selected subgroups in Phase 1 and in Phase 2. CABG, coronary artery bypass graft; HR, heart rate; IABP, intraaortic balloon pump; GFR, glomerular filtration rate; GRACE RS, Global Registry of Acute Coronary Events risk score; MI, myocardial infarction; SBP, systolic blood pressure; TR-pPCI, transradial primary percutaneous coronary intervention.

4. Upon careful patient selection, these results could be achieved also by relatively inexperienced TR operators.
5. The impact of the increasing experience on the procedural results was modest and similar for TR and TF approach.

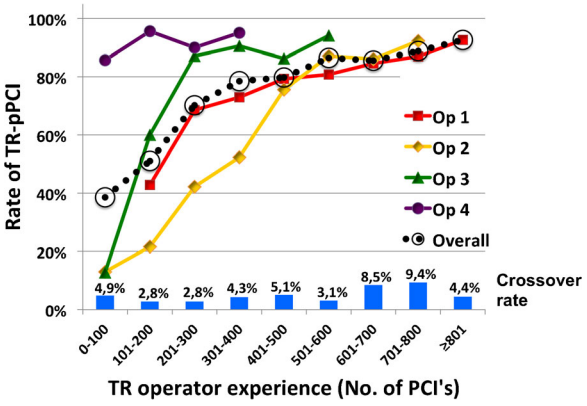

Figure 3. Rate of TR-pPCI and crossover from radial to femoral access according to the radial experience of the operator. Lines indicate the rate of TR-pPCI for the individual operators (solid lines) and overall (dotted line). Bars indicate the crossover rate according to categories of TR experience. Abbreviations as in Figure 1.

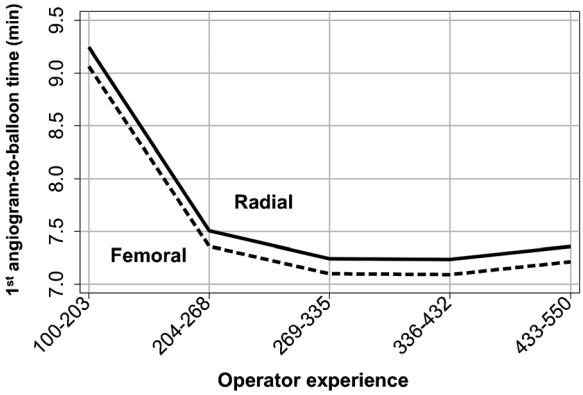

Figure 4. Trend of fitted first angiogram-to-balloon time versus access-related operator experience by vascular approach. The access-related operator experience is the number of procedures already performed by the operator using the same vascular access of the index pPCI. First angiogram-to-balloon time versus experience: P = 0.014; radial versus femoral approach: P = 0.729.

6. TF-pPCI was still preferred, even by experienced radial operators, in some specific high-risk conditions.

Feasibility Rate of TR-pPCI. All operators reached a stable TR-pPCI rate of about 90%, which may be reasonably considered an acceptable target rate in unselected STEMI patients. A TR-pPCI feasibility rate of about 90% was also reported by Gellen et al.,[10] although they excluded patients in cardiogenic shock. From years 2006–2009 (Phase 1) to years 2010–2012 (Phase 2) the TR-pPCI rate increased in all conditions. Even in Phase 2, however, TF-pPCI was still performed in 30–40% of patients with prior CABG or unstable hemodynamics. Clearly, the latter condition impairs the quality of radial pulse, which was the main criterion for the choice of TR-pPCI. Nevertheless, the growing rate of TR approach in hemodynamically unstable patients indicates a lower threshold for the quality of the pulse with increasing experience. The change from first-choice TF to TR-pPCI was relatively slow, requiring 4 years to be completed. Interestingly, this timeline seems consistent to that reported in a large multicenter registry.[11]

Clinical and Procedural Results. The nonrandomized choice of the vascular access and the higher risk profile of the patients treated with TF-pPCI precluded a reliable assessment of the effect of the vascular access on the clinical and procedural results observed in our study. However, no significant

difference in door-to-balloon time, catheterization laboratory entrance-to-balloon time, first angiogram-to-balloon time, fluoroscopy time, and contrast volume between TR and TF approach was evident. There is inconsistency across literature on this important matter. In some studies, the door-to-balloon time was similar with both arterial accesses,[7,12–14] while others reported a longer door-to-balloon time associated with TR intervention.[15–19] A longer fluoroscopy time in TR-pPCI was observed in some studies[6,18,19,20] but not in others.[14,15,17,21] The use of contrast medium was generally not higher in patients undergoing TR-pPCI.[6,15,19] The observed crossover rate from TR to TF access (31 cases, 4.4%) compared favorably to that reported in 2 large randomized trials[6,7] and appeared to be unrelated to operator experience. In addition, when TR and TF patients were compared after stratification by tertiles of GRACE risk score, most differences in baseline characteristics and procedural results disappeared, while TF patients continued to show a significantly higher incidence of hemoglobin drop $\geq$3 g/L in all tertiles of GRACE risk score.

Effect of Operator Experience and Learning Curve. In the studies suggesting a possible mortality benefit linked to TR approach,[6,7] the pPCIs were performed by experienced radial operators. It is unclear whether lesser operator experience could produce a reperfusion delay or procedural complications counterbalancing the benefit of the TR access. In our experience, the crossover from TR to TF access, although occurring in a minority of patients (4.4%), resulted in a much longer door-to-balloon time (median 75 vs. 43 min, $P < 0.001$). Indeed, both U.S.[1] and European[2] guidelines for the management of STEMI express some preference for TR approach for pPCI but only if performed by an experienced radial operator.

Only 1 study has evaluated the learning curve of TR approach specifically in the field of pPCI for STEMI.[22] The present study, however, also compared the relationship between previous experience, assessed separately for TF and TR approach, and procedural results for both access sites. We observed that both operator and center experience in TR approach appeared to be the major determinant of the increasing rate of TR-pPCI over time. Indeed, the transition curve is different among the operators, being steeper for operators that joined our team later, when the center had progressed in the policy change about vascular access. These observations suggest that the policy in vascular access and the radial volume of the center may be at least as important as the experience of the individual operator. Notably, in the RadIal Vs. femorAL access for coronary intervention (RIVAL) trial,[5,6] the volume of the center but not the volume of the operator was associated with better outcome. The influence of access-related operator experience (number of prior PCIs performed by the same access of the index pPCI) on procedural outcome appeared to be quite modest, at least for operator experience $>$100 procedures. In fact, we found no significant association between access-related operator experience and crossover rate, door-to-balloon and catheterization laboratory entrance-to-balloon times, contrast volume, and fluoroscopy time. On the other side, a significant relationship between operator experience and the time from first coronary angiogram to balloon inflation was noted for both access sites. This interval represents the time needed to perform the initial diagnostic angiography, engage the guiding catheter, and cross the lesion. However, the reduction of this adjusted time interval along with increasing experience is quite small (less than 2 min) and arguably lacking prognostic impact, but it might indicate some improvement in the operator skill. The change of slope of the curves at an experience of 200 prior interventional procedures by the same vascular access may suggest that this level of experience could be considered reasonable for a pPCI operator for both vascular approaches. Our observation is in agreement with the recent position paper by the European Association of Percutaneous Cardiovascular Interventions and Working Groups on Acute Cardiac Care and Thrombosis of the European Society of Cardiology,[23] which suggests approaching TR-pPCI after 250 TR cases, including diagnostic ones.

Study Limitations. The main limitations of this study are inherent in its observational nature, with the possibility that unmeasured confounders influenced the results. However, our principal aim was to describe the process of a policy change and the influence of the operator experience on the procedural results, rather than compare the results obtained with either vascular approach. In the evaluation of the learning curve, the pPCIs performed by low-experience operators are underrepresented, because during the study period all operators increased their experience. Along with growing experience, the operators performed more complex procedures, potentially biasing the association between experience and procedural results. In addition, we assessed the first angiogram-to-balloon time, but

not the procedural time, which could have captured smaller differences between the 2 vascular approaches. All patients in this study were treated with unfractionated heparin with a substantial rate of administration of abciximab. Therefore, the observed results may not apply to patients treated with other antithrombotic regimens, such as bivalirudin monotherapy, that demonstrated a marked reduction of bleeding events and mortality.[24] A multicenter randomized study prospectively evaluating the possible synergistic effect of TR-pPCI and use of bivalirudin to minimize bleedings and improve outcomes is currently undergoing.[25]

Conclusions

An effective transition from TF to first-choice TR-pPCI could be implemented over a 4-year period, leading to a stable 90% TR rate in unselected STEMI patients, with a reasonable crossover rate and without increasing delay to reperfusion, contrast volume, and fluoroscopy time. The impact of operator experience on the procedural results, at least after 100 interventional procedures, appeared to be modest and not different for both vascular approaches.

References

1. O'Gara PT, Kushner FG, Ascheim DD, et al. ACCF/AHA guideline for the management of ST-elevation myocardial infarction: A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2013;61:e78–e140.
2. Steg PG, James SK, Atar D, et al. ESC guidelines for the management of acute myocardial infarction in patients presenting with ST segment elevation. Eur Heart J 2012;33:2569–2619.
3. Rao SV, O'Grady K, Pieper KS, et al. Impact of bleeding severity on clinical outcomes among patients with acute coronary syndromes. Am J Cardiol 2005;96:1200–1206.
4. Suh JW, Mehran R, Claessen BE, et al. Impact of in-hospital major bleeding on late clinical outcomes after primary percutaneous coronary intervention in acute myocardial infarction the HORIZONS-AMI (harmonizing outcomes with revascularization and stents in acute myocardial infarction) trial. J Am Coll Cardiol 2011;58:1750–1756.
5. Jolly SS, Yusuf S, Cairns J, et al. Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): A randomised, parallel group, multicentre trial. Lancet 2011;377:1409–1420.
6. Mehta SR, Jolly SS, Cairns J, et al. Effects of radial versus femoral artery access in patients with acute coronary syndromes with or without ST-segment elevation. J Am Coll Cardiol 2012;60:2490–2499.
7. Romagnoli E, Biondi-Zoccai G, Sciahbasi A, et al. Radial versus femoral randomized investigation in ST-segment elevation acute coronary syndrome: The RIFLE-STEACS (radial versus femoral randomized investigation in ST-elevation acute coronary syndrome) study. J Am Coll Cardiol 2012;60:2481–2489.
8. Wiviott SD, Antman EM, Gibson CM, et al. Evaluation of prasugrel compared with clopidogrel in patients with acute coronary syndromes: Design and rationale for the TRial to assess Improvement in Therapeutic Outcomes by optimizing platelet InhibitioN with prasugrel Thrombolysis In Myocardial Infarction 38 (TRITON TIMI 38). Am Heart J 2006;152:627–635.
9. Granger CB, Goldberg RJ, Dabbous O, et al. Predictors of hospital mortality in the Global Registry of Acute Coronary Events. Arch Intern Med 2003;163:2345–2353.
10. Gellen B, Lesault PF, Canouï-Poitrine F, et al. Feasibility limits of transradial primary percutaneous coronary intervention in acute myocardial infarction in the real life (TRAP-AMI). Int J Cardiol 2013;168:1056–1061.
11. Valgimigli M, Saia F, Guastaroba P, et al. Transradial versus transfemoral intervention for acute myocardial infarction: A propensity score-adjusted and -matched analysis from the REAL (REgistro regionale AngiopLastiche dell'Emilia-Romagna) multicenter registry. JACC Cardiovasc Interv 2012;5:23–35.
12. Arzamendi D, Ly HQ, Tanguay JF, et al. Effect on bleeding, time to revascularization and one-year clinical outcomes of the radial approach during primary percutaneous coronary intervention in patients with ST-segment elevation myocardial infarction. Am J Cardiol 2010;106:148–154.
13. Pancholy S, Patel T, Sanghvi K, et al. Comparison of door-to-balloon times for primary PCI using transradial versus transfemoral approach. Catheter Cardiovasc Interv 2010;75:991–995.
14. Weaver AN, Henderson RA, Gilchrist IC, et al. Arterial access and door-to-balloon times for primary percutaneous coronary intervention in patients presenting with acute ST-elevation myocardial infarction. Catheter Cardiovasc Interv 2010;75:695–699.
15. Chodor P, Krupa H, Kurek T, et al. Radial versus femoral approach for percutaneous coronary interventions in patients with acute myocardial infarction. (RADIAMI) A prospective randomized, single center clinical trial. Cardiol J 2009;16:332–340.
16. Chodor P, Kurek T, Kowalczuk A, et al. Radial vs femoral approach with StarClose clip placement for primary percutaneous coronary intervention in patients with ST-elevation myocardial infarction. RADIAMI II: A prospective, randomised, single centre trial. Kardiol Pol 2011;69:763–771.
17. Généreux P, Mehran R, Palmerini T, et al. Radial access in patients with ST-segment elevation myocardial infarction undergoing primary angioplasty in acute myocardial infarction: The HORIZONS-AMI trial. EuroIntervention 2011;7:905–916.
18. Ibebuogu UN, Cercek B, Makkar R, et al. Comparison between transradial and transfemoral percutaneous coronary intervention in acute ST-elevation myocardial infarction. Am J Cardiol 2012;110:1262–1265.
19. Baklanov DV, Kaltenbach LA, Marso SP, et al. The prevalence and outcomes of transradial percutaneous coronary intervention for ST-segment elevation myocardial infarction: Analysis from the national cardiovascular data registry (2007 to 2011). J Am Coll Cardiol 2013;61:420–426.
20. Brasselet C, Tassan S, Nazeyrollas P, et al. Randomised comparison of femoral versus radial approach for percutaneous coronary intervention using abciximab in acute myocardial infarction: Results of the FARMI trial. Heart 2007;93:1556–1561.
21. Saito S, Tanaka S, Hiroe Y, et al. Comparative study on transradial approach vs. transfemoral approach in primary stent implantation for patients with acute myocardial infarction: Results of the test for myocardial infarction by prospective

unicenter randomization for access sites (TEMPURA) trial. Catheter Cardiovasc Interv 2003;59:26–33.
22. Barringhaus KG, Akhter M, Rade JJ, et al. Operator and institutional experience reduces room-to-balloon times for transradial primary percutaneous coronary intervention. J Invasive Cardiol 2014;26:80–86.
23. Hamon M, Pristipino C, Di Mario C, et al. Consensus document on the radial approach in percutaneous cardiovascular interventions: Position paper by the European Association of Percutaneous Cardiovascular Interventions and Working Groups on Acute Cardiac Care and Thrombosis of the European Society of Cardiology. EuroIntervention 2013;8:1242–1251.
24. Stone GW, Witzenbichler B, Guagliumi G, et al. Bivalirudin during primary PCI in acute myocardial infarction. N Engl J Med 2008;358:2218–2230.
25. Valgimigli M, Calabrò P, Cortese B. et al. Scientific foundation and possible implications for practice of the Minimizing Adverse Haemorrhagic Events by Transradial Access Site and Systemic Implementation of AngioX (MATRIX) trial. J Cardiovasc Transl Res 2014;7:101–111.