Original Research

Transradial Access as First Choice for Primary Percutaneous Coronary Interventions: Experience from a Tertiary Hospital in Athens

Spyridon Deftereos[1], Georgios Giannopoulos[1], Konstantinos Raisakis[1], Andreas Kaoukis[1], Charalambos Kossyvakis[1], Loukas Pappas[1], Vasiliki Panagopoulou[1], Aggeliki-Despoina Mavrogianni[2], Andreas Theodorakis[1], Anastasia Perpinia[1], Nikolaos Michelakakis[1], Georgios Bobotis[2], Vlasios Pyrgakis[1]

[1]*Department of Cardiology, Athens General Hospital "G. Gennimatas", Athens,*
[2]*2nd Department of Cardiology, "Papageorgiou" General Hospital, Thessaloniki, Greece*

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Address:
Spyridon Deftereos

Athens General Hospital "G. Gennimatas"
154 Mesogeion Ave.
115 27 Athens, Greece
e-mail: sp.g.deft@gmail.com

Introduction: The transfemoral approach (TFA) has been the mainstay for arterial access during percutaneous coronary intervention (PCI) in the setting of acute ST-segment elevation myocardial infarction (STEMI). However, the transradial approach (TRA) has been shown to be an equally effective and possibly safer way of performing primary PCI (pPCI).

Methods: The study population included 98 serially recruited patients who underwent pPCI in our institution. All patients were clinically followed during their hospital stay (6.4 ± 3.1 days).

Results: In the 98 patients included in the study, 65 procedures (66.3%) were completed via TRA, whereas the remaining 33 procedures (33.7%) used TFA. Door-to-balloon time was similar (57 ± 19 min vs. 54 ± 15 min, p=ns). Patients in the TRA group were mobilized sooner (28 ± 9 hours vs. 36 ± 13 hours, $p<0.05$). Hospital stay was significantly shorter in the TRA group (6.0 ± 3.2 days vs. 7.1 ± 2.8 days, $p<0.05$). TRA and TFA did not differ significantly as to the incidence of death, non-fatal myocardial infarction or subacute stent thrombosis, but major access-related vascular complications were significantly more frequent in the TFA group (2% vs. 15%, $p<0.01$). Cerebrovascular events did not differ between TRA and TFA.

Conclusion: Compared to TFA, TRA seems to be associated with a lower incidence of bleeding complications, as well as earlier mobilization and discharge from hospital. It is conceivable that TRA could become the first choice in the treatment of STEMI patients in the near future, while TFA is kept as an alternative.

The transfemoral approach (TFA) has been until presently the mainstay for arterial access during percutaneous coronary interventions (PCI) in the setting of acute ST-segment elevation myocardial infarction (STEMI), while the transradial approach (TRA) is gaining ground in elective as well as primary procedures. Both minor and major bleeding complications, which are more frequently encountered in patients with STEMI undergoing primary PCI (pPCI) with TFA,[1] have been correlated with increased short- and long-term morbidity and mortality, despite the decrease in periprocedural complication rates observed in recent years.[2,3] TRA, first reported by Kiemeneij and Laarman in 1993, has been shown to be an equally effective and possibly safer way of performing PCI in emergency situations in the hands of experienced interventionists, as it is rarely accompanied by major hemorrhage.[4-6] Additionally, TRA increases patient comfort and gives the opportunity for early discharge, thus reducing the cost of the hospital stay.[7] The main concern related to its use in the setting of STEMI has been, among other issues, a potential delay of reperfusion due to technical difficulties (arterial spasm and local arterial trauma,[8] radio-ulnar loops, subclavian tortuosity, etc.), which are being overcome as more physicians become well trained and acquainted with the technical challenges of this technique.[9]

In this paper, we present the experience of our team of interventional cardiologists, for whom TRA has been the first choice technique for coronary angiography, PCI and pPCI since April 2009. During this period of about 14 months, more than 85% of elective and urgent PCIs in a total of 622 procedures and about 66% of pPCIs in a total of 98 primary angioplasties were performed via TRA.

Methods

Study population

The study population included 98 serially recruited patients who underwent primary PCI in our institution. The clinical and angiographic data of all 98 patients were reviewed retrospectively, and they were separated into two groups according to the arterial route of intervention. TRA was the operators' first choice for angioplasty, especially in cases with a prolonged international normalized ratio (INR) due to treatment with vitamin K antagonists, while TFA was selected in cases of an abnormal Allen test or in patients with coronary artery bypass grafts (CABG) including a left internal mammary artery. PCI was considered as primary if there was ongoing chest pain combined with ST-segment elevation of at least 0.2 mV in two or more contiguous precordial or 0.1 mV in two or more extremity leads. The majority of the patients underwent angioplasty within 12 hours of the onset of symptoms, or later if there was evidence of ongoing ischemia after this time interval. All patients of our study were clinically followed during their hospital stay (6.2 ± 1.5 days).

Anticoagulant and antiplatelet regimen

All patients were administered 320 mg of chewable aspirin and 300-600 mg of clopidogrel at their presentation in the emergency department, as well as an intravenous bolus of 5000 iu of unfractionated heparin (UFH). In the catheterization laboratory, immediately after arterial sheath placement, they were given an additional iv bolus of 100 iu/kg of UFH (maximum dose 10,000 iu) to achieve an activated clotting time of ≥320 s. According to the presence of excessive thrombotic burden, some patients were administered an intracoronary bolus of glycoprotein IIb/IIIa receptor blocking agent (abciximab, eptifibatide or tirofiban), which was continued as an iv infusion for 12 hours after PCI.

Arterial access and coronary interventions

The right femoral artery was punctured with the Seldinger technique under fluoroscopic guidance using a 19 g needle after local administration of 15-20 cc of lidocaine. A J-wire was advanced up into the aorta and a 6 Fr arterial sheath was introduced. A variety of classic angiography and angioplasty catheters were used for the catheterization of the coronary arteries. On completion of the intervention, 10 ml of mixed contrast and saline were injected through the sheath into the femoral artery in order to check for any contrast extravasation and to document whether an Angio-Seal™ STS Plus™ (St. Jude Medical) hemostatic device could be placed. In cases where the sheath was introduced close to the common femoral artery bifurcation, sheath removal was postponed for at least 3 hours (or until activated clotting time fell below 150 s) and hemostasis was achieved via manual compression.

A clinical and oxymetric Allen test was performed before catheterization of the right radial artery. If normal, the latter was accessed after local administration of 1-2 ml of lidocaine with a 20 g needle over which a hydrophilic 0.025" wire was advanced. After cannulation of the radial artery with a 5 or 6 Fr sheath (Terumo co., Japan), 3-4 mg verapamil was given intra-arterially and 3000 iu of UFH heparin intravenously. 5 Fr Tiger II 3.5 catheters were commonly used for diagnostic arteriography of the coronary tree, whereas angioplasty was performed through 5 or 6 Fr catheters (Ikari, Kimny, Amplatz, Judkins and Extra Back-Up). After completion of the procedure, the sheath was immediately removed and hemostasis was achieved with a TR Band™ (Terumo co., Japan) for 3-4 hours or D-Stat Rad Band (Vascular Solutions Inc., MN, USA) for 1-2 hours.

Measured and assessed parameters

The following parameters were recorded: a) time needed (i) to place the sheath, (ii) to dilate the culprit lesion, and (iii) total time of the procedure; b) fluoroscopy time and total X-ray dose; c) crossover from TRA to TFA; d) procedural details (including stent choice, additional devices used, etc.); e) time to mobilization and duration of hospital stay; f) incidence of access site complications (among them, major vascular access complications were defined as those requiring specialized treatment and/or prolongation of hospital stay); and g) MACE (major adverse cardiac events: death, nonfatal myocardial infarction, revascularization of target vessel by PCI) during hospital stay.

Statistical analysis

Statistical analysis was performed using the SPSS version 15.0 statistical software package (SPSS, Inc., Chicago IL, USA). Continuous variables were expressed as mean ± SD and compared using Student's t-test. Categorical variables were expressed as absolute or relative frequencies and compared using chi-square analysis. Binary logistic regression analysis was applied to test the independent associations of various factors and covariates with the composite of major vascular complication or intracranial bleeding or ischemic cerebrovascular event entered as the dependent variable. A p-value <0.05 was considered statistically significant.

Results

Baseline characteristics of the study patients

In the 98 patients (48 men, age 64 ± 8 years) included in the study, 65 procedures (66.3%) were completed via TRA, whereas the remaining 33 procedures (33.7%) used TFA. Baseline demographic and clinical characteristics of the study patients are shown in Table 1. There were no statistically significant differences between any characteristics in the two groups of patients, except for the history of CABG and the abnormal Allen test, which were reasons for selecting TFA, and treatment with *per os* anticoagulants, which was an indication for TRA. Angioplasty in saphenous vein grafts was performed in just one case in the TFA group and concerned a graft to the right coronary artery.

Angiographic and procedural characteristics

The patients' angiographic and procedural characteristics are given in Table 2. With the exception of crossover to other access site and the use of a vascular closure device, there were no statistically significant differences between the two groups. It should be stressed that access site crossover took place only in TRA patients and was caused by radial artery spasm (3 cases), radio-ulnar loop (1 case), extreme tortuosity of the right subclavian artery leading to permanent wire placement in the descending aorta (1 case) and lack of sufficient backup of the guide catheter (1 case). Despite the eventual need to puncture the femoral artery, the delay in the whole procedure was not significant. Indeed, in the six patients of the TRA group in whom crossover was necessary to complete the coronary intervention the door-to-balloon time was 59 ± 12 min, which did not differ significantly from the times of both the rest of the TRA group and the TFA group (respectively 56 ± 17 min and 54 ± 15 min, p = 0.64).

Table 1. Baseline demographic and clinical characteristics of patients treated with transradial (TRA) versus transfemoral (TFA) access.

	TRA (n=65)	TFA (n=33)	p
Age (years)	65 ± 7	63 ± 8	NS
Male gender	48 (74%)	25 (76%)	NS
Diabetes mellitus	20 (30%)	9 (27%)	NS
Smoking	25 (38%)	12 (36%)	NS
Hypertension	32 (49%)	16 (48%)	NS
Dyslipidemia	24 (37%)	15 (45%)	NS
Family history of CAD	9 (14%)	5 (15%)	NS
Previous MI	12 (18%)	7 (21%)	NS
Previous PCI	14 (22%)	5 (15%)	NS
Ejection fraction (%)	45 ± 2	44 ± 2	NS
Previous CABG	0 (0%)	2 (6%)	0.01
Treatment with VKA	3 (5%)	0 (0%)	0.01
Abnormal Allen test	0 (0%)	9 (27%)	0.01

Continuous and graded variables are expressed as mean ± SD. Categorical variables are expressed as count (percentage).
CAD – coronary artery disease; MI – myocardial infarction; PCI – percutaneous coronary intervention; CABG – coronary artery bypass grafting; VKA – vitamin K antagonist.

Table 2. Angiographic and procedural characteristics for transradial (TRA) versus transfemoral (TFA) access.

	TRA (n=65)	TFA (n=33)	p
Door-to-balloon time (min)	57 ± 19	54 ± 15	NS
Door-to-sheath time (min)	48 ± 15	46 ± 12	NS
Sheath-to-culprit vessel cannulation time (min)	5 ± 2	5 ± 3	NS
Total procedure time (min)	55 ± 17	53 ± 15	NS
Fluoroscopy time (min)	20 ± 9	22 ± 10	NS
X-ray dose (cGy/cm^2)	12.07 ± 7.25	12.32 ± 8.10	NS
Access site crossover	6 (9%)	0 (0%)	0.01
Guide catheters per procedure (n)	1.35 ± 0.72	1.21 ± 0.69	NS
Balloons per procedure (n)	1.61 ± 0.52	1.42 ± 0.51	NS
Stents per procedure (n)	1.51 ± 0.65	1.63 ± 0.68	NS
DES per procedure (n)	0.80 ± 0.42	0.95 ± 0.51	NS
IVUS	12 (18%)	7 (21%)	NS
Glycoprotein IIb/IIIa inhibitors	36 (55%)	19 (58%)	NS
Thromboaspiration devices	11 (17%)	6 (18%)	NS
No-reflow phenomenon	6 (9%)	4 (12%)	NS
Vascular closure device	65 (100%)	24 (73%)	0.01
Diseased vessels (stenosis >50%)	1.7 ± 0.7	1.9 ± 0.4	NS
Presence of non-culprit diseased vessels (revascularized after 2-3 days)	25 (38%)	13 (39%)	NS
Culprit RCA lesion combined with left main or ostial LAD disease	2 (3%)	1 (3%)	NS
Culprit LAD or LCx lesion combined with left main disease	1 (2%)	1 (3%)	NS

Total procedure time indicates time from sheath placement to hemostasis device placement. Continuous and graded variables are expressed as mean ± SD. Categorical variables are expressed as count (percentage).
DES – drug eluting stent; IVUS – intravascular ultrasound; RCA – right coronary artery; LAD – left anterior descending; LCx – left circumflex.

Time to mobilization and duration of hospital stay

Patients of the TRA group were mobilized sooner compared to TFA patients and the difference was statistically significant as regards both ability to sit up in bed (12 ± 7 hours vs. 19 ± 12 hours, $p<0.05$) and ability to walk across the ward (28 ± 9 hours vs. 36 ± 13 hours, $p<0.05$). The same difference was observed concerning the length of hospital stay, which was significantly less in the TRA group (6.0 ± 3.2 days vs. 7.1 ± 2.8 days, $p<0.05$). The most frequent reasons for prolonged hospital stay in any of the two groups were vascular access site complications, post-infarct angina, contrast-induced nephropathy and PCI of non-culprit diseased vessels, which usually took place 2-3 days after the pPCI.

MACE and access-related vascular complications during hospital stay

MACE during hospital stay and vascular complications are reported in Table 3. TRA and TFA did not differ significantly as to the incidence of death, nonfatal myocardial infarction or subacute stent thrombosis, but local hematomas and major vascular complications were significantly more frequent in the TFA group ($p<0.01$). More specifically, in the TFA patients 6 cases of local hematoma and 2 cases of retroperitoneal hematoma were recorded, of which 4 required transfusion, and 1 case of pseudoaneurysm formation was treated with the intervention of a vascular surgeon. In the TRA group only 2 cases of local hematoma were encountered and just 1 patient had a major vascular complication (compartment syndrome of the arm requiring fasciotomy). No TRA patient required a blood transfusion. Intracranial bleeding did not differ significantly between the two groups.

In the applied multivariate model of binary logistic regression analysis, the route of arterial access, age, gender, cardiovascular risk factors, use of oral anticoagulants before catheterization, use of glycoprotein IIb/IIIa inhibitors, history of known coronary artery disease, history of cerebrovascular disease, number of implanted stents and ejection fraction were entered as independent variables. Femoral arterial access (multivariate $p=0.032$; 95% confidence interval of odds ratio 1.21-7.29) and female gender (multivariate $p=0.025$; 95% confidence

Table 3. Adverse cardiovascular events during hospital stay for transradial (TRA) versus transfemoral (TFA) access.

	TRA (n=65)	TFA (n=33)	p
Death (n)	2 (3.1%)	2 (6.1%)	NS
Non-fatal AMI (n)	1 (1.5%)	1 (3.0%)	NS
Subacute stent thrombosis and repeat PCI (n)	1 (1.5%)	1 (3.0%)	NS
Local hematoma (n)	2 (3.1%)	6 (18.2%)	p<0.01
Major vascular complications (n)	1 (1.5%)	5 (15.2%)	p<0.01
Intracranial bleeding (n)	1 (1.5%)	1 (3.0%)	NS
Ischemic cerebrovascular event (n)	1 (1.5%)	1 (3.0%)	NS

Variables are expressed as count (percentage).
AMI – acute myocardial infarction; PCI – percutaneous coronary intervention.

interval of odds ratio 1.03-2.31) were independent predictors of the composite of major vascular complication/intracranial bleeding/ischemic cerebrovascular event.

Discussion

The aim of this paper is to report our one-center experience concerning the implementation of TRA in the field of primary angioplasty and to show that this strategy is at least equivalent to TFA, as far as safety and timeliness are concerned, and probably more advantageous when access site vascular complications, early mobilization and discharge are considered.

During the past decade, several studies have demonstrated the disastrous impact of major hemorrhage after pPCI on the mortality of STEMI patients.[2,10] Recently, Hermanides et al[10] presented the results of a large scale study, reporting that major bleeding complications were strongly and independently correlated with short- and mid-term mortality. Similar evidence has also been shown in other studies including urgent PCI in patients with unstable angina and NSTEMI.[11] In our study, both major vascular complications and local hematomas were more frequent in the TFA group, and this difference was statistically significant. Our results agree with those of other studies that demonstrated that the incidence of combined vascular and bleeding complications was lower with the TRA than with TFA.[1,12] In a systematic meta-analysis, Jolly et al[13] showed that TRA was associated with a 73% reduction in the incidence of major bleeding compared to TFA, while there was also a trend towards fewer adverse cardiovascular events with TRA. This kind of trend, identified in the meta-analysis of Jolly et al, was observed as a significant difference between TRA and TFA in the study of Arzamendi et al,[14] where TRA was associated with fewer deaths, major cardiovascular events and bleeding complications compared to TFA in patients treated with pPCI for STEMI.

The above-mentioned evidence implies that transradial intervention could probably be accompanied by reduced short- and long-term mortality in the setting of STEMI, but this certainly needs to be further assessed by a large randomized trial. In any case, regardless of whether TRA will truly prove to be associated with lower mortality in the context of pPCI, the fact that it leads to less bleeding appears to be a generally accepted notion; this is most likely the grounds on which the Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) in the Guidelines on Myocardial Revascularization[15] specifically recommend the use of "radial access in patients at high risk of bleeding", even though this recommendation does not assume the status of a formal guideline.

In tight relation to the reduced incidence of major bleeding complications in TRA, early mobilization of the patients improves their comfort and early discharge from hospital, and should increase the cost-effectiveness of coronary interventions, especially in large tertiary centers where insufficient bed capacity is an ongoing concern.[14] Our results are in agreement with this observation, which has also been documented in other studies, such as that of Dirksen et al,[17] where most STEMI patients managed transradially with pPCI and receiving tirofiban could be discharged early (within 4 days) without an increase of MACE. Similarly, in our study over half of the patients in each group received treatment with glycoprotein IIb/IIIa inhibitors, but those in the TRA group were able to exit hospital sooner.

An important finding of our study is the fact that door-to-balloon time in TRA patients did not differ significantly from that of the TFA group. Indeed, there was no significant delay in the definitive management of STEMI patients, even in the cases of crossover from TRA to TFA (this is explainable by the fact that the right femoral artery is always prepped for puncture, even when TRA is the initial choice, so little additional time is needed to gain access transfemorally). The importance of this finding is obvious, as it is widely known that during the first hours of an AMI "time is myocardium" and that the time consumed until the opening of the culprit lesion is critical for the patient's outcome.[18] Our observation is in accordance with other recent studies that compared the two approaches in the setting of pPCI.[1,19,20]

Limitations

A limitation of our study is that it was not randomized. Transradial access was the operators' first choice in all patients, except when specific features (i.e. CABG including a left internal mammary artery graft, or abnormal Allen test) were present. Nevertheless, the two groups of patients had no statistically significant difference between them as far as their epidemiologic and clinical features were concerned. Furthermore, the nature of this study was observational, aiming at reporting the experience of our catheterization laboratory concerning the initial implementation of use of TRA in the setting of pPCI.

Conclusions

Our study, based on the experience of our catheterization lab team, shows that TRA for pPCI in patients with STEMI constitutes an effective and safe method of approaching this high-risk group of patients. Compared to TFA, transradial intervention seems to be associated with a lower incidence of both major and minor bleeding complications and earlier mobilization and discharge from the hospital. We consider it conceivable that TRA could become the first choice in the treatment of these patients in the near future. The transfemoral approach can be kept as an alternative in cases with an abnormal Allen test or with a history of CABG, although the continuously improving technical level of the operators in transradial procedures may extend the applicability of TRA to some of these cases as well.

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