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# Feasibility Limits of Transradial Primary Percutaneous Coronary Intervention in Acute Myocardial Infarction in the Real Life (TRAP-AMI)

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## **ABSTRACT**

**BACKGROUND** There is growing evidence that transradial (TRI) as compared to transfemoral (TFI) percutaneous coronary intervention (PCI) is associated with improved clinical outcome driven by less hemorrhagic complications, in particular in STEMI patients receiving aggressive antithrombotic treatment. Feasibility rate of TRI in STEMI patients has not yet been evaluated.

**METHODS / RESULTS** Four-hundred seventy-five consecutive STEMI patients (<12h) without cardiogenic shock were prospectively screened for this all-comer single-centre registry between January 2008 and August 2010. Nine patients were excluded for a priori ineligibility for TRI (forearm shunt for dialysis, prior TRI failure). In the 466 patients enrolled, the operator's opinion about ease of radial puncture was assessed in 4 categories, based on radial pulse quality. Operators were advised not to attempt TRI if ease of puncture was judged "probably difficult / impossible". In case of puncture failure the operator switched immediately to TFI.

The mean age of patients was 61±14 (range 27-94) years. Seventy-three percent were men, 17% had diabetes. Nine percent had previous PCI. Glycoprotein inhibitors were used in 70%, and thrombectomy was performed in 70% of patients. PCI was performed using 6F and 5F guiding catheters. Procedural success rate was 98.2% (TIMI flow  $\geq 2$ ).

In 4.1% (n=19) of patients the operator judged ease of radial puncture "probably difficult / impossible" and no TRI attempt was performed (primary TFI). In the 447 patients with TRI attempt, TRI failure requiring switch to TFI (secondary TFI) was necessary in 22 patients (4.7% of total) following radial puncture failure (n=15), dissection of the radial artery (n=1), prohibitive tortuosities or stenosis of the upper limb axis (n=2), or non-selective position or lack of stability of the guiding catheter (n=2). After starting of the angioplasty procedure, switch from TR to TF was not necessary in any patient. In total, the overall feasibility rate of TRI was 91.2%. Independent predictors of final TFI were age  $\geq 80$  years (adjusted OR: 2.37; 95% CI:1.05-5.34, p=0.037), body weight < 60 kg (adjusted OR: 2.84; 95% CI:1.22-6.59, p=0.015); and previous PCI (adjusted OR: 3.42; 95% CI:1.40-8.37, p=0.007); female gender was borderline significant (adjusted OR:2.10; 95% CI:0.97-4.54, p=0.059).

**CONCLUSION** In STEMI patients without cardiogenic shock and without a priori indication for TFI, PCI can be performed via the radial artery in more than 90% of cases with high procedural success rate. Operator's judgement of eligibility for TRI based on radial pulse quality is predictive of successful TRI in 95% of cases. TR failure is significantly more common in the elderly and in patients with low body weight.

## INTRODUCTION

The radial artery is accepted as a suitable access for diagnostic coronary angiography (CAG) and percutaneous coronary intervention (PCI). Subsequently, transradial intervention (TRI) has become a progressively widespread practice<sup>1,2</sup>. As compared with transfemoral intervention (TFI), TRI is associated with fewer puncture site bleeding complications<sup>3-6</sup>, decreased length of hospital stay<sup>7</sup>, and lower hospital costs<sup>8</sup>.

Patients with ST-segment elevation myocardial infarction (STEMI) referred for primary PCI are usually treated with ASA, thienopyridines, heparin, and most of them receive glycoprotein inhibitors (GPI). This aggressive antiplatelet and anticoagulation regimen successfully reduced cardiac ischemic events at cost of increased rate of hemorrhagic complications<sup>9,10</sup>. With regard to the causal relationship between major bleeding in PCI patients and increased mortality and morbidity<sup>3,11</sup>, the use of the radial access might be particularly beneficial in the STEMI population. Indeed, the recently published large REAL registry found a more than 50% reduction in vascular complications and decreased 2-year risk-adjusted mortality in STEMI patients with TRI as compared to TFI<sup>12</sup>.

Even if TRI is considered technically more delicate than TFI<sup>13</sup>, experimented teams report TRI feasibility rates in clinically stable patients of up to 98%<sup>14-16</sup> without significant increase in total procedure duration<sup>17</sup>. The high success rate without prolongation of procedural length encouraged a growing number of interventional cardiology (IC) teams to use TRI in STEMI patients. Several observational studies report high feasibility rates and excellent safety of TRI in this high risk population and the emergency context<sup>17-21</sup>. Small single-centre randomized trials have addressed the issue of femoral versus radial access in the setting of AMI, finding similar success rate of reperfusion and comparable<sup>22,23</sup> or reduced<sup>24</sup> access site-related complication rate in TRI as compared to TFI. These results were corroborated by the large randomised RIVAL trial conducted in patients with acute coronary syndrome, finding a lower rate of access site-related complications in the TRI as compared to the TFI subgroup<sup>25</sup>. Finally, a recent meta-analysis of 9 randomized TRI vs. TFI trials including almost 3000 STEMI patients found a 37% reduction of major bleedings associated with a significantly reduced mortality in patients with TRI<sup>26</sup>.

Feasibility rates of TRI in patients with acute coronary syndrome derived from randomized studies are however not transposable to an all comer real-life population, since in these studies only patients eligible for both TRI and TFI are included resulting in selection of patients with good quality radial pulse. Moreover, reasons for TRI failure are not indicated hampering detailed analysis of patient- and operator-related conditions. We hypothesized that in a non pre selected STEMI population a well trained TRI team can achieve a TRI success rate above 90%.

The primary objective was therefore to evaluate the proportion of hemodynamically stable STEMI patients who can benefit from TRI in a real-world setting. Secondary objectives were to identify factors associated with final TFI as defined by primary choice of femoral access or failure of TRI, and to quantify time loss associated with TRI failure.

## **MATERIALS AND METHODS**

### **Study centre and investigators**

This registry was conducted at Mondor University Hospital, Créteil/France, a high procedural volume centre with more than 2000 coronary angiograms and about 1200 PCI procedures per year, and an 8 year experience in transradial catheterization. Over the past five years, more than 80% of all coronary angiograms and PCIs have been performed via the radial artery in our centre.

For the present study, the recruiting interventional cardiologists (IC) team consisted of 9 physicians. Five of them had a less than 2 years experience in interventional cardiology and had performed less than 1000 angioplasties prior to the inclusion period (junior ICs).

The authors of this manuscript certify that they comply with the principles of ethical publishing in the International Journal of Cardiology<sup>27</sup>.

### **Patient recruitment**

Patients were consecutively and prospectively enrolled between January 2008 and August 2010. Inclusion criteria were defined by acute coronary syndrome within 12 hr from onset with ST segment elevation  $\geq 1$  mm in 2 or more contiguous leads associated with sustained chest pain for more than 30 minutes, and the presence of coronary lesions corresponding to the ECG territory. Patients with cardiogenic shock (Killip class 4) and patients with a priori indication for femoral access (known prior TRI failure; forearm shunt for dialysis; both left and right internal mammary artery bypasses) were not included. Patients were recruited either from the emergency unit of our hospital, mobile intensive care units, or were referred from other hospitals. All patients underwent coronary angiography and ad hoc PCI if necessary. Patients with successful thrombolysis received a control angiogram within 24 hours. Secondary (rescue) PCI was performed in patients with failed thrombolytic therapy.

### **Choice of arterial access**

Pulse quality of both radial arteries was systematically assessed. If pulse quality was equivalent, the right radial artery was preferred. In patients eligible for TRI, the operator switched immediately to the femoral artery in case of radial failure. There was no switch to the contra lateral radial artery in order to limit time loss.

Guedes et al. have recently proposed three categories for subjective evaluation of radial pulse quality (strong / normal / weak), radial artery size (large / normal / small), and operator's opinion about ease of puncture (easy / normal / difficult)<sup>16</sup>. In the present study a comparable approach was applied, based on four categories : for radial pulse quality 1) strong, 2) normal, 3) weak, or 4) imperceptible; for radial artery size 1) large, 2) normal, 3) small, or 4) very small / absent; and for operator's opinion about ease of puncture 1) easy, 2) normal, 3) potentially difficult, or 4) probably difficult / impossible. In patients with ease of puncture judged "probably difficult / impossible" for both radial arteries, the femoral access was chosen without TRI attempt (primary TFI). In all other patients TRI was tempted. In patients with ease of

radial puncture judged “potentially difficult”, the femoral access was pre prepared (shaved and disinfected) prior to radial puncture attempt in order to limit time loss.

### **Pre-treatment and arterial puncture**

All patients were pre treated with an intravenous bolus of 50-70 IU/kg unfractionated heparin or 0.5 mg/kg enoxaparin and an intravenous bolus of 250 mg aspirin. Conscious patients were administered 300-600 mg clopidogrel orally, with an upper limit of 75 mg for patients older than 75 years. No glycoprotein IIb/IIIa antagonists were given prior to PCI. Patients with pre hospital thrombolysis received an intravenous bolus of tenecteplase by the physician of the mobile intensive care unit.

For TRI, the skin overlying the radial artery was anesthetized by local infiltration using 1-2 ml of lidocaine. After radial artery puncture, a 6 or 5 Fr short sheath (70mm) was inserted according to the Seldinger technique. Thereafter, a cocktail consisting of 1 mg of isosorbide dinitrate and 2.5 mg of verapamil was injected into the sheath in order to facilitate catheter progression and to prevent arterial spasm.

Immediately after PCI the sheath was removed and compression (using a tourniquet) was applied for 4 hr. For TFI, a 6 Fr / 110mm sheath was inserted following local anaesthesia with 10-20ml lidocaine. After PCI the sheath was removed immediately and haemostasis was achieved either by femoral closure device (Angioseal<sup>®</sup>, St Jude Medical) or manual compression for 10 min with subsequent pressure bandage for 12 hr.

### **PCI procedure**

Angioplasty was performed according to the current ESC guidelines for PCI in STEMI. Patients with angiographic thrombus were administered glycoprotein IIb/IIIa antagonists prior to angioplasty in absence of contraindications, and thrombus aspiration was performed using the Export<sup>®</sup> (Medtronic) or Proxis<sup>®</sup> (StJude) thrombectomy device. After publication of the TAPAS trial<sup>28</sup> thrombectomy was performed systematically in all STEMI patients. Procedural success was defined as TIMI flow  $\geq 2$  in the culprit coronary artery.

### **Data analysis**

Baseline characteristics of patients with TRI and final TFI were compared using Pearson  $\chi^2$  test or Fisher test and Student T-test or Wilcoxon Mann-Whitney for qualitative and quantitative data respectively. All factors associated with TFI in univariate analysis with  $p < 0.15$  were considered for multivariate analysis.

The performance of senior and junior ICs was compared in order to detect a possible influence of the operator’s experience. Two-by-two analyses were used to assess first-order interactions and confounding by fitting multiplicative models. A final logistic model was then built with the factors independently associated with final TFI. In order to take account of the hierarchical structure of the data a multilevel

logistic regression model was also applied, giving similar estimations for odds ratios and 95% confidence intervals. A *P* value of less than 0.05 was considered statistically significant.

Quantitative data are reported as mean ( $\pm 1$  SD) or median (interquartile range [IQR]: 75<sup>th</sup> minus 25<sup>th</sup> percentile) as appropriate. Qualitative variables are reported as number (%). All comparisons were two-sided and *P* values smaller than 0.05 were considered significant. The data were analyzed using the Stata (StataCorp 2005, Release 11.0, College Station, TX, USA) statistical software.

## RESULTS

### Patient characteristics, arterial access, coronary intervention, and in-hospital outcome

Five-hundred thirty-nine STEMI patients were admitted during the inclusion period, of which 64 (11.9%) were in cardiogenic shock requiring inotropic support and were not screened for this registry. The relatively high prevalence of cardiogenic shock is due to a recruitment bias of our hospital which is the only centre in the Val-de-Marne district with cardiac surgery providing ECMO. Among the remaining 475 patients screened, 9 patients with a priori indication for femoral access were excluded, and 466 were finally enrolled (**Figure 1**). The baseline demographic and clinical characteristics of study patients are presented in **Table 1**. In 19 patients (4.1 %) PCI was performed right away via the femoral artery without TRI attempt (primary TFI). The remaining 447 (95.9%) patients underwent a single TRI attempt. In 425 of these patients (95.1%) the PCI procedure could be completed via the radial artery. In the remaining 22 patients (4.9%) TRI failed and the procedure was converted into TFI (secondary TFI). Thus, in total 41 patients needed TFI (final TFI). The femoral access did not fail in any patient. None of the patients required switch to TFI for LV assist device during the procedure.

Ninety-one percent of all TRI failures were related to the radial artery, with the leading cause being inability to promptly catheterize the radial artery (**Figure 2**). TRI failure for reasons that were not directly related to the upper limb arterial axis occurred only in 2 patients (insufficient support and non-selectivity of the guiding catheter, respectively). Procedural characteristics of coronary interventions are summarized in **Table 2**. There were no significant differences in characteristics of the angioplasty procedure between patients with TRI and those with final TFI.

Operator's judgement was predictive of 98.5% (396 of 401) of TRI success if ease of radial puncture was judged "easy" or "normal", whereas ease of puncture judged "potentially difficult" was predictive of TRI success only in 63% (29 of 46, **Table 3**). Door-to-balloon/aspiration time was comparable between TRI and primary TFI procedures. TRI failure was associated with a statistically significant average time loss of 12-15 minutes as compared to TRI and primary TFI, respectively. All significant bleeding complications related to the access site (N=4) occurred in the primary TFI group, responsible for hemorrhagic shock in three patients. Access site-related haemorrhage did not lead to in-hospital death in any patient.

### Patient characteristics associated with final TFI

The baseline characteristics of patients with TRI and of those with final TFI (primary or secondary TFI) were compared (**Table 1**). Patients with final TFI were more frequently  $\geq 80$  years old, of female gender, non smokers (borderline significant), had lower body mass, smaller body size and lower BMI.

In multivariable analysis, age  $\geq 80$  years, body mass  $< 60$  kg, previous PCI, and female gender (borderline significant) were independently predictive of final TFI (**Figure 3**). The associations between height, smoking and final TFI disappeared after adjustment for sex. No interaction was found between



variables of the final multivariable model. Due to co-linearity with body mass, BMI was not included in the final multivariable model.

In patients with previous PCI (N=44) we know that at least one of the previous procedures was performed via the radial access in 24 cases. Six other patients with previous PCI performed more than 10 years earlier, before TRI has started to become a widespread practice in France, did certainly not have TRI or TRI attempt. In 6 other cases PCI was performed after 2000 via the femoral access. It can not be excluded that some of these patients had unsuccessful TRI attempts that were not documented in the previous PCI report. In the remaining 8 patients with PCI in the early 2000 the access site was not indicated in the PCI report.

### **Operator's experience**

The nine interventional cardiologists performed 7-94 (1.5-20.2 %) PCIs per operator. The proportion of final TFI varied from 0 to 22.2%. The proportion of primary TFI varied from 0 to 13.0% without significant difference ( $p=0.14$  and  $p=0.30$  respectively), and for secondary TFI from 0 to 22.2% with borderline significant difference ( $p = 0.054$ ). The weight of the operator-related variability was only 8.2% of the global variability of final TFI (explained by patient characteristics and cardiologist's experience) as estimated in the multilevel model.

Operator's level of experience (senior/junior) was not significantly associated with rate of primary choice of femoral access (5.06% versus 3.21%;  $p=0.34$ ), with secondary TFI due to TRI failure (3.94% versus 6.22%;  $p=0.27$ ), or with final TFI (8.61% versus 9.05%;  $p=0.87$ ).

## DISCUSSION

The major findings of the present study was to show 1) that more than 90% of patients in a non-selected, hemodynamically stable STEMI population could safely benefit from the radial approach for primary PCI, and 2) that age  $\geq$  80 years, body weight  $<$  60 kg, previous PCI, and possibly female gender were independent predictors of TFI.

The radial approach has clearly demonstrated its advantages as compared to TFI, with regard to patient comfort and bleeding complications<sup>25</sup>. In STEMI patients reperfusion rates in primary PCI were reported to be comparable in TRI and TFI<sup>29</sup>. In this population receiving aggressive antiplatelet and anticoagulation treatment, TRI seems to be particularly superior to TFI with regard to haemorrhagic complications<sup>30</sup>. In total, the excellent feasibility and safety of TRI-PCI encourage a growing number of interventional cardiology teams to use the radial access for PCI.

As reported exhaustively in the literature, angioplasty of culprit lesions in STEMI patients can be performed using standard 6F guiding catheters and first-choice guide-wires<sup>13,29,31</sup>, allowing to comfortably perform thrombectomy and more complex PCI. Indeed, in our registry none of the PCI procedures required guiding catheters of more than 6F. Reperfusion failures were related to persistent no-reflow in the culprit artery rather than to technical difficulties to treat the culprit lesion. Thus, mismatch between the diameter of the guiding catheter and the radial artery lumen seems not to be a significantly limiting factor for primary TRI-PCI.

In the past, feasibility rates of transradial PCI were exclusively evaluated in stable clinical settings where time is not a determining factor. The very high success rates of 97-98 % found in these studies<sup>14,16</sup> can be explained by the fact that operators could take their time with repeated radial puncture attempts, with time-consuming strategies to overcome tortuous anatomy, stenosis or spasm of the upper limb arterial axis, and with switch to the opposite radial artery in case of definite cannulation failure<sup>16</sup>. However, in the setting of STEMI where loss of time can be equivalent with loss of muscle and worse clinical outcome, such time-consuming strategies are not acceptable. Transradial primary PCI should only be considered in these patients if prompt cannulation success is highly probable, and if the catheterization laboratory team is well prepared to switch to TFI immediately in case of TRI failure.

We consider therefore that, in contrast to elective PCI, the femoral access should remain the first choice in STEMI patients with elevated risk of technically difficult radial artery puncture. Consequently, it is crucial to identify patients with high risk for potentially time consuming or technically impossible radial cannulation, such as particularly small radial artery diameter and/or particularly weak pulse of both radial arteries as assessed by rapid clinical examination.

In our registry, 4% of patients were considered not eligible for TRI attempt based on this single clinical criterion. Interestingly, we observed no significant difference between the rate of primary choice of femoral access between senior and junior ICs, nor in TRI failure rate in patients considered eligible for TRI. These facts taken together suggest a relatively steep learning curve for the clinical evaluation of radial pulse quality and for the technical mastery of radial cannulation.

In line with previously published data<sup>32,33</sup>, door-to-balloon/aspiration time was not longer in TRI as compared to primary TFI patients. However, in patients with TRI failure (4.7%) switch to the femoral access has accounted for prolongation of the door-to-balloon/aspiration time. Even if the conversion of TRI to TFI is relatively quick in a well prepared team, it remains evident that all preventive measures should be undertaken to reduce the number of TRI failures. Therefore, pre-selection of patients based uniquely on the subjective evaluation of radial pulse quality might be insufficient, and simple clinical criteria such as sex, age, and body size might help to reduce TRI failure rate. Of note is that in line with recent data published by Guedes et al.<sup>16</sup>, inability to puncture or to wire the radial artery accounted for the majority of TRI failures in our cohort. This is of crucial importance since in these patients failure of the radial access is stated within minutes after beginning of the procedure, limiting time loss.

Success rate of transradial PCI depends - in addition to arterial pressure - on radial artery diameter, on presence of atherosclerotic lesions and/or tortuosities of the upper limb arterial axis, and on previous use of the artery for invasive procedures such as PCI or arterial pressure monitoring in intensive care units. It is common knowledge that smaller body size is more frequent among women and that it is associated with smaller vessel diameters. It is also well established that atherosclerosis and arterial tortuosities are more prevalent in the elderly. It was therefore expected that in univariable analysis female gender, body size, body weight and advanced age would be significantly associated with final TFI. However it is somewhat surprising that in multivariable analysis low body weight still remains an independent predictor of need for TFI in contrast to small body size, since body weight depends on lifestyle and nutrition whereas body size is constitutional.

The role of previous PCI as an independent predictor of final TFI is more delicate to interpret. In case of previous transradial PCI, the radial artery can be partially or completely occluded making subsequent radial puncture difficult or impossible. On the other hand, patients with previous PCI had by definition pre-existing atherosclerotic arterial disease and constitute therefore a subpopulation with increased risk for non-coronary atherosclerotic lesions that might involve the upper limb arterial axis.

The vast majority of TRI failures occurred in patients in which ease of puncture was judged “potentially difficult” by the operator. Since TRI failure inevitably leads to a limited but significant time loss and thereby to prolonged myocardial ischemia, it remains a matter of debate if in these patients TRI should be attempted even if in almost two-third of cases TRI could be successfully performed. The major argument in favour of attempting TRI despite mediocre radial pulse quality and/or small size of the radial artery, mostly observed in the elderly with low body weight, is that the same population exhibits the highest rate of complications related to TFI<sup>34</sup>. The fact that in our study all major access site-related hemorrhagic complications occurred in the primary TFI group and none in the secondary TFI group might be at least in part explained by disseminated atherosclerotic disease in these patients leading to poor radial pulse quality and concomitantly to increased femoral puncture / closure complications. In light of these facts we consider that also in STEMI patients with increased risk of TRI failure due to constitutional factors TRI

should remain the first choice; however the catheterization laboratory team should be particularly well prepared for switch to TFI in order to minimize time loss.

### **Limitations of the study**

Pre hospital recruitment bias is probably limited, since our hospital is the only primary hospital with catheterization laboratory in the Val-de-Marne district draining almost all STEMI patients via the mobile intensive care units in a region with 1.3 million inhabitants. A centre effect can not be excluded. Operator-related bias is probably limited since procedures were performed by 9 interventional cardiologists with different levels of experience. Due to the low proportion of final TFI, this study was underpowered for separate analysis of factors associated with primary TFI and secondary TFI after TRI failure.

### **CONCLUSION**

More than 90% of hemodynamically stable STEMI patients can safely benefit from the radial access for PCI. TRI failure is more common in elderly patients, in patients with low body weight and in patients with previous PCI. A large scale prospective study is needed 1) for establishing a simple clinical score aimed at improving patient pre-selection, and 2) to evaluate if the time loss in patients with TRI failure has a measurable impact on clinical outcome.

### **ACKNOWLEDGEMENTS**

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### **DISCLOSURES**

The authors have no conflict of interests to disclose in connection with the present work.

	TOTAL	TRI	final TFI	p value *
	n=466	n=425	n=41	TRI vs. TFI
Age (years)	61.1 ± 14.4	61.0 ± 13,9	62.4 ± 19.0	0.55
≥ 80 years	61 (13.1)	49 (11.5)	12 (29.3)	<b>&lt;0.001</b>
Men	342 (73.4)	322 (75.8)	20 (48.8)	<b>&lt;0.0001</b>
Diabetes	79 (17.0)	69 (16.3)	10 (24.3)	0.19
Smokers	280 (60.1)	261 (61.4)	19 (46.3)	<b>0.06</b>
Hypertension	197 (43.3)	176 (41.4)	21 (51.2)	0.23.
Hyperlipidemia	182 (39.1)	163 (38.4)	19 (46.3)	0.33
Weight (kg)	76.1 ± 14.6	76.6 ± 14.2	70.8 ± 17.5	<b>0.016</b>
weight < 60 kg	49 (10.5)	37 (8.7)	12 (29.3)	<b>0.0001</b>
weight ≥ 90 kg	91 (19.6)	84 (19.8)	7 (17.1)	0.67
Height (cm)	169.7 ± 8.7	170.2 ± 8.4	164.5 ± 9.8	<b>&lt;0.0001</b>
height ≤ 160 cm	81 (17.9)	64 (15.5)	17 (43.6)	<b>&lt;0.0001</b>
BMI (kg/m <sup>2</sup> )	26.4 ± 4.2	26.4 ± 4.1	25.9 ± 4.8	0.42
BMI ≥ 30	93 (20.5)	84 (20.3)	9 (23.1)	0.68
BMI ≤ 25	188 (41.5)	166 (40.1)	22 (56.4)	0.048
Previous MI	34 (7.3)	30 (7.1)	4 (9.8)	0.53
CABG	3 (0.6 %)	3 (0.7)	0 (0)	1.00
Previous PCI	44 (9.4 %)	36 (8.5)	8 (19.5)	<b>0.021</b>

**Table 1: Baseline characteristics for TRI and final TFI**

TRI=transradial intervention; TFI=transfemoral intervention; BMI=body mass index; MI=myocardial infarction; PCI=percutaneous coronary intervention; CABG=coronary artery bypass graft;

Data were in n (%) or mean (SD) for qualitative and quantitative variables respectively.

\*Pearson  $\chi^2$  or Fisher test for qualitative variables; Student T-test for quantitative variables

	<b>TOTAL</b>	<b>TRI</b>	<b>final TFI</b>	<b>p value *</b>
	<b>n=466</b>	<b>n=425</b>	<b>n=41</b>	<b>TRI vs. TFI</b>
<b>Multivessel disease</b>	247 (53)	225 (52.9)	22 (53.7)	0.93
<b>Culprit artery</b>				
<b>LAD</b>	190 (40.8)	168 (39.5)	22 (53.7)	0.17
<b>CX</b>	83 (17.8)	80 (18.8)	3 (7.3)	
<b>RCA</b>	192 (41.2)	176 (41.4)	16 (39.0)	
<b>main left</b>	0 (0)	0 (0)	0 (0)	
<b>saphenous graft</b>	1 (0.2)	1 (0.2)	0 (0)	
<b>sheat size</b>				
<b>6F</b>	460 (98.7)	420 (98.8)	40 (97.6)	0.43
<b>5F</b>	6 (1.3)	5 (1.2)	1 (2.4)	
<b>use of GP IIb/IIIa antagonist</b>	335 (71.9)	312 (73.4)	23 (56.1)	0.019
<b>PCI performed</b>	448 (96.1)	411 (96.7)	37 (90.2)	0.06
<b>thrombectomy</b>	327 (70.2)	305 (71.8)	22 (53.7)	0.016
<b>stenting</b>	419 (89.9)	384 (90.3)	35 (85.4)	0.28
<b>final TIMI flow <math>\geq</math> 2</b>	455 (97.6)	415 (97.6)	40 (97.6)	1.00

**Table 2: Procedural characteristics**

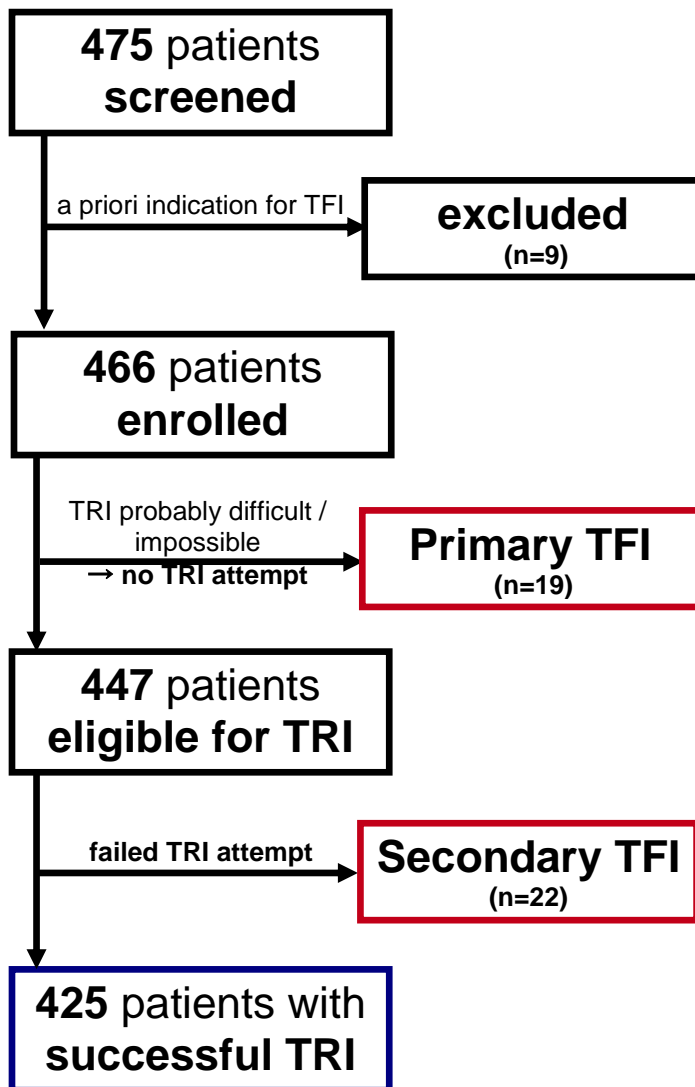
LAD=left anterior descendent ; CX=circumflex ; RCA=right coronary artery ; GP=glycoprotein ; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

**Table 3: Radial pulse quality, procedure duration, hemorrhagic complications and mortality**

	<b>TOTAL</b>	<b>TRI</b>	<b>primary TFI</b>	<b>second.TFI</b>	<b>p value *</b>
	<b>466</b>	<b>n=425</b>	<b>n=19</b>	<b>n=22</b>	
<b>Operator's opinion about ease of radial puncture</b>					
<b>Easy</b>	320 (68.6)	316 (74.5)	0	<b>3 (13.6)</b>	<b>&lt;0.001</b>
<b>Normal</b>	81 (17.4)	79 (18.6)	0	<b>2 (9.1)</b>	
<b>Potentially difficult</b>	46 (9.9)	29 (6.8)	0	<b>17 (77.3)</b>	
<b>Probably difficult / imposs.</b>	19 (4.1)	0 (0.0)	19 (100.0)	<b>0(0.0)</b>	
<b>Door-to-balloon time (min)</b>	33 (25-42)	30 (25-40)	33 (26-35)	<b>45.5 (39-54)</b>	<b>&lt;0.001</b>
<b>Hemorrhagic complications</b>					
<b>Intracranial bleeding</b>	2 (0.4)	2 (0.5)	0(0.0)	0 (0.0)	-
<b>Access site bleeding</b>	4 (0.9)	0 (0.0)	4(21.0)	0 (0.0)	-
<b>Blood transfusion</b>	13 (2.8)	10 (2.4)	3 (15.8)	0(0.0)	0.03
<b>In hospital death</b>	11 (2.4)	10 (2.4)	0 (0.0)	1 (4.6)	-
<b>Death related to bleeding</b>	2(0.4)	2 (0.5)	0(0.0)	0(0.0)	-
<b>Length of hospital stay (d)</b>	3 (3-4)	3 (3-4)	4 (3-7)	3(3-4)	0.25

Data were in n (%) or median (Q1-Q3) for qualitative and quantitative variables respectively.

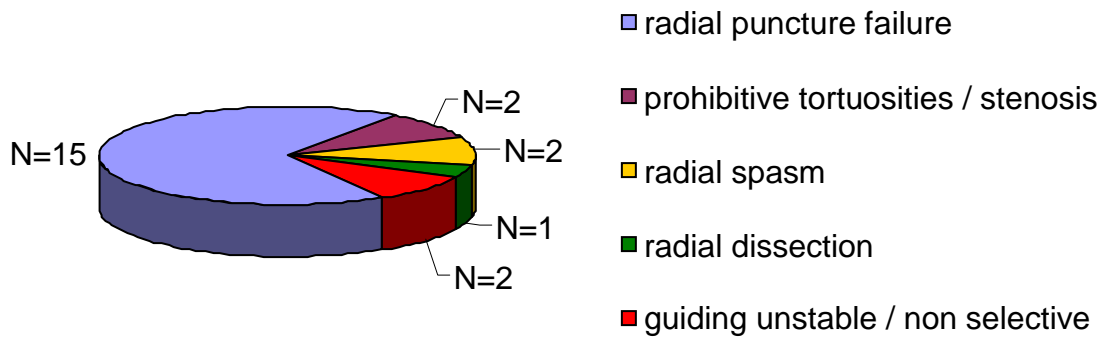
\*Pearson  $\chi^2$  or Fisher test for qualitative variables; Student T-test for quantitative variables



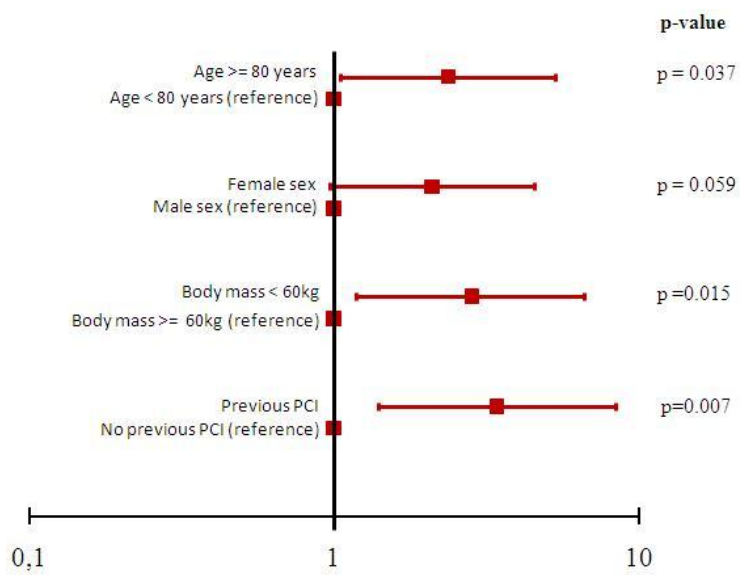
**Figure 1: Flow chart of study patients**

TRI=transradial intervention; TFI=transfemoral intervention





**Figure 2: Reasons for radial access failure (n=22)**



**Figure 3:** Adjusted odds ratios for final TFI

Odds ratios and 95% confidence intervals were estimated using multilevel logistic regression adjusted for all variables listed in the figure

## BIBLIOGRAPHY

1. Cheng CI, Wu CJ, Fang CY, Youssef AA, Chen CJ, Chen SM, Yang CH, Hsueh SK, Yip HK, Chen MC, Fu M, Hsieh YK. Feasibility and safety of transradial stenting for unprotected left main coronary artery stenoses. *Circ J*. 2007;71:855-61.
2. Small A, Klinke P, Della Siega A, Fretz E, Kinloch D, Mildenerger R, Williams M, Hilton D. Day procedure intervention is safe and complication free in higher risk patients undergoing transradial angioplasty and stenting. The discharge study. *Catheter Cardiovasc Interv*. 2007;70:907-12.
3. Hamon M, Filippi-Codaccioni E, Riddell JW, Lepage O. Prognostic impact of major bleeding in patients with acute coronary syndromes. A systematic review and meta-analysis. *EuroIntervention*. 2007;3:400-8.
4. Rao SV, Ou FS, Wang TY, Roe MT, Brindis R, Rumsfeld JS, Peterson ED. Trends in the prevalence and outcomes of radial and femoral approaches to percutaneous coronary intervention: a report from the National Cardiovascular Data Registry. *JACC Cardiovasc Interv*. 2008;1:379-86.
5. Agostoni P, Biondi-Zoccai GG, de Benedictis ML, Rigattieri S, Turri M, Anselmi M, Vassanelli C, Zardini P, Louvard Y, Hamon M. Radial versus femoral approach for percutaneous coronary diagnostic and interventional procedures; Systematic overview and meta-analysis of randomized trials. *J Am Coll Cardiol*. 2004;44:349-56.
6. Sciahbasi A, Pristipino C, Ambrosio G, Sperduti I, Scabbia EV, Greco C, Ricci R, Ferraiolo G, Di Clemente D, Giombolini C, Lioy E, Tubaro M. Arterial access-site-related outcomes of patients undergoing invasive coronary procedures for acute coronary syndromes (from the ComPaRison of Early Invasive and Conservative Treatment in Patients With Non-ST-ElevatiOn Acute Coronary Syndromes [PRESTO-ACS] Vascular Substudy). *Am J Cardiol*. 2009;103:796-800.
7. Cruden NL, Teh CH, Starkey IR, Newby DE. Reduced vascular complications and length of stay with transradial rescue angioplasty for acute myocardial infarction. *Catheter Cardiovasc Interv*. 2007;70:670-5.
8. Roussanov O, Wilson SJ, Henley K, Estacio G, Hill J, Dogan B, Henley WF, Jarmukli N. Cost-effectiveness of the radial versus femoral artery approach to diagnostic cardiac catheterization. *J Invasive Cardiol*. 2007;19:349-53.
9. Pannu R, Andraws R. Effects of glycoprotein IIb/IIIa inhibitors in patients undergoing percutaneous coronary intervention after pretreatment with clopidogrel: a meta-analysis of randomized trials. *Crit Pathw Cardiol*. 2008;7:5-10.
10. Ali A, Hashem M, Rosman HS, Moser L, Rehan A, Davis T, Romanelli M, LaLonde T, Yamasaki H, Barbish B, Michael J, Ali SA, Schreiber TL, Gardin JM. Glycoprotein IIb/IIIa receptor antagonists and risk of bleeding: a single-center experience in 1020 patients. *J Clin Pharmacol*. 2004;44:1328-32.
11. Manoukian SV, Feit F, Mehran R, Voeltz MD, Ebrahimi R, Hamon M, Dangas GD, Lincoff AM, White HD, Moses JW, King SB, 3rd, Ohman EM, Stone GW. Impact of major bleeding on 30-day mortality and clinical outcomes in patients with acute coronary syndromes: an analysis from the ACUITY Trial. *J Am Coll Cardiol*. 2007;49:1362-8.
12. Valgimigli M, Saia F, Guastaroba P, Menozzi A, Magnavacchi P, Santarelli A, Passerini F, Sangiorgio P, Manari A, Tarantino F, Margheri M, Benassi A, Sangiorgi MG, Tondi S, Marzocchi A. 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.
13. Louvard Y, Ludwig J, Lefevre T, Schmeisser A, Bruck M, Scheinert D, Loubeyre C, Klinghammer L, Morice MC, Flachskampf FA, Daniel WG. Transradial approach for coronary angioplasty in the setting of acute myocardial infarction: a dual-center registry. *Catheter Cardiovasc Interv*. 2002;55:206-11.
14. Valsecchi O, Vassileva A, Musumeci G, Rossini R, Tespili M, Guagliumi G, Mihalcsik L, Gavazzi A, Ferrazzi P. Failure of transradial approach during coronary interventions: anatomic considerations. *Catheter Cardiovasc Interv*. 2006;67:870-8.

15. Lo TS, Nolan J, Fountzopoulos E, Behan M, Butler R, Hetherington SL, Vijayalakshmi K, Rajagopal R, Fraser D, Zaman A, Hildick-Smith D. Radial artery anomaly and its influence on transradial coronary procedural outcome. *Heart*. 2009;95:410-5.
16. Guedes A, Dangoisse V, Gabriel L, Jamart J, Chenu P, Marchandise B, Schroeder E. Low rate of conversion to transfemoral approach when attempting both radial arteries for coronary angiography and percutaneous coronary intervention: a study of 1,826 consecutive procedures. *J Invasive Cardiol*. 2010;22:391-7.
17. Valsecchi O, Musumeci G, Vassileva A, Tespili M, Guagliumi G, Gavazzi A, Ferrazzi P. Safety, feasibility and efficacy of transradial primary angioplasty in patients with acute myocardial infarction. *Ital Heart J*. 2003;4:329-34.
18. Mulukutla SR, Cohen HA. Feasibility and efficacy of transradial access for coronary interventions in patients with acute myocardial infarction. *Catheter Cardiovasc Interv*. 2002;57:167-71.
19. Kim MH, Cha KS, Kim HJ, Kim SG, Kim JS. Primary stenting for acute myocardial infarction via the transradial approach: a safe and useful alternative to the transfemoral approach. *J Invasive Cardiol*. 2000;12:292-6.
20. Yan ZX, Zhou YJ, Zhao YX, Liu YY, Shi DM, Guo YH, Cheng WJ. Safety and feasibility of transradial approach for primary percutaneous coronary intervention in elderly patients with acute myocardial infarction. *Chin Med J (Engl)*. 2008;121:782-6.
21. Ochiai M, Isshiki T, Toyozumi H, Eto K, Yokoyama N, Koyama Y, Takeshita S, Sato T. Efficacy of transradial primary stenting in patients with acute myocardial infarction. *Am J Cardiol*. 1999;83:966-8, A10.
22. Saito S, Tanaka S, Hiroe Y, Miyashita Y, Takahashi S, Tanaka K, Satake S. 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.
23. Chodor P, Krupa H, Kurek T, Sokal A, Swierad M, Was T, Streb W, Duszanska A, Swiatkowski A, Honisz G, Kalarus Z. 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;16:332-40.
24. Brasselet C, Tassan S, Nazeyrollas P, Hamon M, Metz D. Randomised comparison of femoral versus radial approach for percutaneous coronary intervention using abciximab in acute myocardial infarction: results of the FARMi trial. *Heart*. 2007;93:1556-61.
25. Jolly SS, Yusuf S, Cairns J, Niemela K, Xavier D, Widimsky P, Budaj A, Niemela M, Valentin V, Lewis BS, Avezum A, Steg PG, Rao SV, Gao P, Afzal R, Joyner CD, Chrolavicius S, Mehta SR. Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): a randomised, parallel group, multicentre trial. *Lancet*. 2011;377:1409-20.
26. Mamas MA, Ratib K, Routledge H, Fath-Ordoubadi F, Neyses L, Louvard Y, Fraser DG, Nolan J. Influence of access site selection on PCI-related adverse events in patients with STEMI: meta-analysis of randomised controlled trials. *Heart*. 2012;98:303-11.
27. Coats AJ. Ethical authorship and publishing. *Int J Cardiol*. 2009;131:149-50.
28. Svilaas T, Vlaar PJ, van der Horst IC, Diercks GF, de Smet BJ, van den Heuvel AF, Anthonio RL, Jessurun GA, Tan ES, Suurmeijer AJ, Zijlstra F. Thrombus aspiration during primary percutaneous coronary intervention. *N Engl J Med*. 2008;358:557-67.
29. Hetherington SL, Adam Z, Morley R, de Belder MA, Hall JA, Muir DF, Sutton AG, Swanson N, Wright RA. Primary percutaneous coronary intervention for acute ST-segment elevation myocardial infarction: changing patterns of vascular access, radial versus femoral artery. *Heart*. 2009;95:1612-8.
30. Siudak Z, Zawislak B, Dziewierz A, Rakowski T, Jakala J, Bartus S, Noworolnik B, Zasada W, Dubiel JS, Dudek D. Transradial approach in patients with ST-elevation myocardial infarction treated with abciximab results in fewer bleeding complications: data from EUROTRANSFER registry. *Coron Artery Dis*. 2010;21:292-7.

31. Ruzsa Z, Ungi I, Horvath T, Sepp R, Zimmermann Z, Thury A, Jambrik Z, Sasi V, Toth G, Forster T, Nemes A. Five-year experience with transradial coronary angioplasty in ST-segment-elevation myocardial infarction. *Cardiovasc Revasc Med.* 2009;10:73-9.
32. Pancholy S, Patel T, Sanghvi K, Thomas M, Patel T. Comparison of door-to-balloon times for primary PCI using transradial versus transfemoral approach. *Catheter Cardiovasc Interv.* 2010;75:991-5.
33. Weaver AN, Henderson RA, Gilchrist IC, Ettinger SM. 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;75:695-9.
34. Wiviott SD, Braunwald E, McCabe CH, Montalescot G, Ruzyllo W, Gottlieb S, Neumann FJ, Ardissino D, De Servi S, Murphy SA, Riesmeyer J, Weerakkody G, Gibson CM, Antman EM. Prasugrel versus clopidogrel in patients with acute coronary syndromes. *N Engl J Med.* 2007;357:2001-15.