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Transradial versus transfemoral access for female patients who underwent primary PCI in STEMI: Two years follow-up data from acute STEMI interventional registry

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ABSTRACT

Background: Female patients possess a higher risk for poorer outcome in ST segment elevation myocardial infarction (STEMI). There is possibility that transradial access (TRA) for primary percutaneous coronary intervention (PPCI) could provide better outcome than transfemoral access (TFA) in female patients with STEMI.
Methods: From 2008 to 2010, 418 female patients (out of 1808 patients) underwent PPCI for acute STEMI. The registry recruited all-comers patients with acute STEMI. Cardiac mortality, major bleeding, and overall MACE rates (composite of death, stroke, re MI and target vessel revascularization-TVR) after 2 years follow-up were compared between TRA and TFA.
Results: TRA for PPCI was performed in 261 patients and 157 underwent TFA PPCI. The 30-days, 1 year mortality and 2 year mortality rates were lower in TRA compared to TFA (6.9% vs.14.6%, $p = 0.012$, 8.8% vs. 15.3%, $p = 0.045$, and 9.2% vs. 16.6%, $p = 0.027$respectively). After 2 years follow-up, the overall MACE rates were similar (26.4% vs. 31.2%, $p = 0.336$). The overall major bleeding and major vascular access site bleeding were more favorable for TRA than TFA (4.4 vs. 14%, $p < 0.001$, and 2.7 vs. 10.8%, $p < 0.001$, respectively).
Conclusion: Transradial access for primary PCI in female patients provided better clinical outcomes with lower cardiac mortality and reduced major bleeding in comparison to TFA. There was no significant difference at 2 years MACE between TRA and TFA.

1. Introduction

Acute coronary syndrome, particularly acute myocardial infarction, is the leading cause of death in many countries [1–3]. It has been projected that it still be the main cause of mortality and disability over the year of 2020 [4]. In patients presenting with acute ST elevation myocardial infarction (STEMI), primary percutaneous coronary intervention (PPCI) is recommended reperfusion therapy when it can be performed in a timely fashion by experienced operators in a PCI-capable center [5]. Various ways have been introduced to get better outcome for patients who underwent PPCI, such as optimal antiplatelet therapies and improvement procedural related aspects. Access site is an important procedural aspect related to the successful of a PCI procedure, including PPCI. Transfemoral access (TFA), which was previously used as the main access for PCI, has been associated with substantially higher risks of bleeding and transfusions than transradial access (TRA) as shown in a recent meta-analysis [6]. Recent randomized trial, as well as data registry from our center, revealed that TRA has less bleeding events, lower vascular access site complication and better clinical outcome compared with transfemoral access (TFA) in STEMI patients undergoing PPCI in acute STEMI [7–9].

Female gender has been known to possess poorer outcome in STEMI [10]. Previous studies have also reported worse in-hospital and long-term mortality of women undergoing elective PCI by TFA [11,12]. On the other hand, radial approach may decrease access site–related bleeding in women undergoing elective PCI [12]. Anatomically, radial artery is more superficial, and close proximity to the radial bone, which makes haemostasis easier than TFA [13]. Whether these benefits of TRA would result in better clinical outcomes for female patients who underwent PPCI in the setting of acute STEMI remains to be defined.

In the present study, we sought to compare the outcome of female patients who underwent PPCI in acute STEMI with TRA and the default TFA.

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2. Methods

2.1. Study population

With the growing evidences on the favorability of TRA in PCI, our center has completely transformed from default TFA to TRA in 2011. During the transitional period of default TFA to TRA within the year of 2008 to 2010, there were 1808 patients underwent PPCI in acute STEMI included in the registry. The registry recorded all comers with acute STEMI, irrespective of clinical presentation. All procedures were done by 7 interventional cardiologists who have experienced in performing PCI both by TFA or TRA. All of these operators have performed at least 100 elective PCI's by TRA before commenced to do PPCI by TRA. Decision to do the PCI by TFA or TFA was left to the discretion of the operator. The results of cohort in overall 1808 patients in the registry have been published recently [9]. We selected all female patients recruited in the registry for the present study. The operator immediately entered the data of each case to the registry after the procedure. The data of registry was open to the health administration and public health insurance administration.

2.2. Interventional procedures

The details of PPCI procedure has been described elsewhere [9]. Briefly, a modified Seldinger technique was performed to obtain TFA. After local infiltration with 3- 5 ml 2% lidocaine, the femoral artery was punctured with a 17G needle and 0.035 in. guide-wire, followed by 10 cm 6Fr introducer sheath placement. On TRA, radial artery was accessed after local infiltration with 1–1.5 ml 2% lidocaine, using counter puncture technique with a 20G plastic iv cannula and 0.025 in. mini guide-wire of 45 cm, and followed by 6Fr hydrophilic introducer sheath placement. The spasmolytic cocktail of 5 mg verapamil was administered through the sheath.

To perform PPCI, standard guiding catheters (such as: Judkins, EBU, Amplatz, etc.), mostly 6Fr and sometimes 5Fr, for both TRA and TFA were used. The guide-wires for PCI, mostly Balance Middle Weight (Abbott Vascular, USA) were used as indicated by the operator's judgment. The stents choice was left to the operator's consideration. Flow of infarct-related artery was evaluated before and after the PPCI procedure using the TIMI (Thrombolysis in Myocardial Infarction) score. Manual thrombus aspiration was selectively performed in the cases with high thrombus burden and TIMI 0 flow. PCI only on the infarct related artery was done with the main goal to reach the TIMI-3 flow [14].

Standard medications in acute STEMI were given to all patients. These include aspirin (300 mg followed by 100 mg/day indefinitely), clopidogrel (loading dose 600 mg followed by 75 mg/day for at least 1 year), as well as intravenous bolus of unfractioned heparin (70 IU/kg), when required, abciximab was given intracoronary or intravenous bolus of 0.25 mg/kg followed by 0.125 μg/kg/min infusion for 12 h. After completion of PCI, weight adjusted dosage protocol of heparin infusion was continued for 24 h or 12 h protocol of abciximab. No fibrinolytic agent was used during PPCI.

Sheath removal for TFA was done after 3–4 h from the sheath insertion, and haemostasis was achieved by manual compression of 15–20 min followed by prolonged weight compression placement. Patient must remain in bed thereafter, with restricted mobility, in the following six hours (9–10 h in total from the sheath insertion). On TRA, the arterial sheath was removed immediately after the procedure. Haemostasis was achieved by a simple bandage compression or TR band (Terumo, Japan). The simple bandage compression was applied with 2–4 small elastic bands compressing the radial artery at the puncture site. The TR band was applied by inflating 11–15 ml of air at the puncture site. The TR band was gradually deflated each hour after procedure, and removed after four hours. Patients had no mobility restriction after the procedure.

2.3. Study end-points

The primary end-points for this study purposes were cardiovascular death and the major cardiovascular events (MACE) within 30 days, 1 year, and 2 years. The MACE was composite of death, stroke, re-MI, and target vessels revascularization. The secondary end-points consist of: overall major bleeding, major vascular access site bleeding and major non-access site bleeding in 30 days [15]. Comparison of baseline- and procedural characteristics between TRA and TRA were also evaluated. The baseline characteristics include variables of demography and clinical presentations. Meanwhile procedural-related characteristics during PPCI consist of variables: culprit lesions, diseased vessels, IABP use, time frame related, and contrast use.

Cardiovascular death includes cardiovascular related death, includes: death in acute MI, sudden cardiac death, death due to heart failure, death due to stroke, death due to cardiovascular procedures, death due to cardiovascular hemorrhage, and death due to other cardiovascular causes. Major vascular access bleeding was defined as any access site related hemorrhage requiring red blood cell transfusion, delayed hospital discharge or requiring a surgical vascular repair [15]. Major non access bleeding was defined as overt clinical bleeding (or documented intracranial or retroperitoneal hemorrhage) associated with a drop in hemoglobin of 5 g/dL, or in hematocrit of 15% not related to the access site [16]. Term of overall major bleeding refers to a Bleeding Academic Research Consortium (BARC) 3 or 5 [17]. Time from onset to intervention was defined as time from onset of acute STEMI symptoms to the start of PPCI. Meanwhile, procedural time was defined as time from puncture arterial access until the time of guide-catheter pulled out from the sheath at the end of PPCI.

2.4. Statistical analysis

Continuous variables were expressed as mean ± standard deviation for normally distributed data and median with the range (maximum-minimum) for data that not fitting with normal distribution. Comparison of continuous data between TRA and TFA was performed with Student *t*-test or Mann-Whitney *U* test when appropriate. Categorical variables were presented in numbers and percentage, and comparison between the groups was done by Chi-square test or Fischer exact test. Clinical outcome of PPCI between TFA and TRA group was analyzed by univariate log-regression and reported as odds ratio (OR) with the corresponding 95% confidence intervals (CI), calculated for the endpoints. Survival curves were constructed using Kaplan-Meier techniques, and comparisons were made by Mantel-Cox log rank test. The significances were considered for $p < 0.05$.

3. Results

During transitional period of default TFA to TRA for PCI within the year of 2008 to 2010, there were 1808 patients with acute STEMI that underwent PPCI. Among them 418 women were included in the present study. Their median age was 62 years old (range of 30–86 years). The PPCI was done 261 (62.4%) with TRA, and 157 with TFA (37.6%). Major cardiovascular risk factors were similar between the groups of TRA and TFA. History of major comorbidities such as previous: PCI, CABG, and renal insufficiency were not significantly different between the two groups. Clinical presentations in the time of PPCI include: anterior MI, cardiogenic shocks, and time of MI onset to intervention were also similar between the groups of TRA and TFA. Those baseline characteristic comparing TRA and TFA is listed in the Table 1.

During PPCI procedure, the most frequent culprit lesion finding was in the left anterior descending (LAD) coronary artery both in the group of TRA (49.8%), and in TFA (45.9%). The culprit lesion in the bifurcation part of coronary arteries was more frequent in the TRA group (18.8%) than in the TFA (8.9%). Angiographic results during PPCI showing associated coronary disease such as diseases in the LM trunk and the multivessel involvement were not different between TRA and TFA. Most of patients were with pre-interventional TIMI flow 0–1 in the culprit lesion that was not significantly different in TRA (74.7%) and TFA (79.0%). The overall PPCI procedures success of culprit vessels reaching TIMI 3 flow was similar between TRA and TFA (91.2% vs. 91.7%). The time frame related during PPCI included: door to balloon time, procedural time, and fluoroscopic time were not different between the groups of TRA and TFA. The PPCI by TRA consumed significantly less amount of contrast than in the TFA ($p < 0.001$). The overall PPCI procedural-related characteristics in TRA and TFA are presented in the Table 2.

3.1. Primary and secondary end-points

At 30 days after PPCI, the death incidence of female patients with acute STEMI was significantly lower in TRA group than TFA (6.9 vs. 14.6%, $p = 0.012$). At 1 year and 2 years follow up, the cumulative

Table 1
Baseline characteristics.

Variables	TRA (N = 261)	TFA (N = 157)	p value
Risk factors & comorbidities			
Age, years	62.4 ± 10.5	60.3 ± 9.6	0.05
Diabetes	89 (34.1)	56 (35.7)	0.41
Hypertension	181 (69.3)	108 (68.8)	0.49
Dyslipidemia	99 (37.9)	63 (40.1)	0.36
Smoker	89 (34.1)	50 (31.8)	0.35
Family history	40 (15.3)	22(14.0)	0.41
Previous PCI	14 (5.4)	12 (7.6)	0.23
Previous CABG	0 (0.0)	1 (0.6)	0.37
Previous CHF	4 (1.5)	5 (3.2)	0.21
Renal insufficiency	3 (1.1)	2 (1.3)	0.62
Clinical presentations			
Anterior MI	130 (49.8)	72 (45.9)	0.25
Cardiogenic shock	8 (3.1)	7 (4.5)	0.31
Onset to intervention, min (IQR)	230 (40–960)	254 (30–870)	0.24

Data are presented as number (percentages) or mean ± SD, unless otherwise stated.
TRA: transradial access; TFA: transfemoral access; PCI: percutaneous coronary intervention; CABG: coronary artery bypass graft; CHF: congestive heart failure; MI: myocardial infarction; IQR: interquartile range.