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Original Article

Risk factors of failed transradial approach for percutaneous coronary interventions in Chaoshan Chinese: a locally retrospective analysis

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Abstract: Background: Transradial approach PCI reduces vascular complications compared with a transfemoral approach (TFA). TRA-PCI failure has been reported in 5-10% of cases. Reported studies showed that age > 75 years, previous CABG, short stature, female sex, and cardiogenic shock were independent predictors of TRA-PCI failure. However, related risk factors and causes of TRA-PCI failure are not well characterized, especially among Asians. Objectives: To explore the risk factors and causes of transfemoral approach (TRA)-PCI failure in Chaoshan area. Methods: We retrospectively analyzed our databases for all patients who underwent TRA-PCI from January 2011 to June 2014 in the First Affiliated Hospital of Shantou University Medical College. Univariate and multivariate analyses were performed to determine independent risk factors of TRA-PCI failure and the causes of TRA-PCI failure. Results: A total of 1,276 patients underwent TRA-PCI. From univariate analyses, patients in the TRA-PCI failure group were significantly in women, and more likely to be age > 75 years compared with TRA-PCI success group. Besides, patients in the TRA-PCI failure group were significantly more likely to suffer from left main coronary disease, more heparin dose, longer fluoroscopy time, and more PCI procedural failure compared with the TRA-PCI successful group. From multivariate analysis, female and age > 75 years were independent predictors of TRA-PCI failure. The causes of TRA-PCI failure included unsuccessful radial artery puncture in 34, vascular anomaly in 54, and the problems of guide catheter and guide wire in 26 patients. Conclusions: Being female and age > 75 years were independent risk factors of TRA-PCI failure. TRA-PCI failures indicated more possibility to suffer from left main coronary disease. The causes of TRA-PCI failure were complicated, among of those vascular abnormalities was an important factor.

Keywords: Risk factors, transradial approach, percutaneous coronary intervention

Introduction

Percutaneous coronary intervention has been well accepted as one of the main methods for the treatment of coronary heart disease (CHD). Transradial and transfemoral approaches are both safe and effective for PCI. However, transradial approach for coronary angiography and intervention is being increasingly adopted worldwide. Transradial approach have been shown to offer many benefits over transfemoral approach, including fewer bleeding and vascular complications, decreased time to ambulation, shorter length of hospital stay, lower healthcare costs, and improved prognosis of patients [1-7]. It was proposed that TRA should be recommended as the primary method of interventional in patients with ACS [8]. In the RIFLE-STEACS research, the 30-day rate of net adverse clinical events of radial access in patients with ST-segment elevation acute coronary syndrome is associated with significant clinical benefits, in terms of both lower morbidity and cardiac mortality [9]. However, the radial artery approach failed for a small number of patients, leading to delays of increasing the myocardial of survival or prolonged operation time and even failure. It was also showed that age > 75 years, previous CABG, short stature, female sex, cardiogenic shock were independent predictors of TRA-PCI failure [10, 11]. But the related risk factors and causes of TRA-PCI

failure are unclear for Asians at present, and there is no related risk factors research in the range of China.

Therefore, we retrospectively analyzed our databases for TRA-PCI. The purposes of this study is aimed to determine what related risk factors of TRA-PCI failure, and the causes of TRA-PCI failure.

Methods

Study population

The retrospectively analyzed population consisted of all patients who underwent TRA-PCI from January 2011 to June 2014 in the First Affiliated Hospital of Shantou University Medical College. The program was approved by Shantou University Medical College ethics committee. All patients' indication for TRA-PCI was confirmed by experienced cardiologists and radial artery was tested by Allen test before PCI. No consent was necessary for this analysis, and all patients' information was anonymized and de-identified prior to analysis. Using the Computerized Patient Record System to collect and record all the patients' age, sex, hypertension history, diabetes history, dyslipidemia, renal insufficiency, PCI history, smoking history, indication for PCI, coronary arteries, intervened coronary artery, heparin dose, fluoroscopy time, contrast volume, GP IIb/IIIa, stents, procedural failure, and, if any, reasons for TRA-PCI failure. The patients with directly transfemoral approach or incomplete information were excluded. Using the excel spreadsheets double record and check it.

TRA-PCI procedure

TRA-PCI was defined as undergoing percutaneous coronary intervention from the transradial approach. TRA-PCI failure was defined as inability to complete a PCI procedure by TRA, requiring secondary TFA. Procedural failure was defined as incompletion of PCI procedure from TRA with < 10% residual stenosis and Thrombolysis In Myocardial Infarction (TIMI) flow grade 3 in the intervened artery, or found the major adverse cardiac events (death, myocardial infarction, or need for revascularization (surgical or percutaneous) during in hospital. All procedures were done by experienced cardiologist.

Using a dedicated arm board, and with the patient's wrist slightly hyperextended, the right radial artery was cannulated after administration of 2 to 3 ml of local anesthetic, with a short, beveled, 19-gauge bare needle or 18-gauge needle. A soft 0.035-inch straight guidewire was then advanced into the radial artery lumen, and a 10-cm 5-to 6-F nonhydrophilic introducer sheath (Terumo Medical Corporation, Elkton, Maryland) was placed into the radial artery. In case of faint radial pulse, subcutaneous 200 mg of nitroglycerin was sometimes used at the time of local anesthesia. Fluoroscopy or selective angiography of radial, brachial, or subclavian artery was only performed if difficulty was encountered in advancing the guidewire or catheters. After sheath insertion, an initial bolus of 50 IU/kg of unfractionated heparin was administered intravenously. Where appropriate, glycoprotein IIb/IIIa inhibitor was at the discretion of the physician in charge of the case. The radial sheath was removed in the operating room immediately after completion of the procedure, and hemostasis achieved by application of a locally designed adjustable plastic bracelet (Terumo Medical Corporation, Elkton, Maryland). Per protocol, the bracelet was loosened every 60 min until hemostasis was achieved, usually within 6 h. All procedures were performed by low-to-intermediate volume TRA-PCI operators (with a minimum case volume of 50 PCI procedures per annum).

The patients with stable angina were pre-treated with the loading dose of aspirin and clopidogrel. The patients with acute coronary syndrome were pre-treated with 300 mg of aspirin and 300~600 mg of clopidogrel. All patients with post-operation were taken with 100 mg/d of aspirin and 75 mg/d clopidogrel. The patients with acute coronary syndrome post-operation were subcutaneous injected 0.4 ml of low molecular weight heparin q12 h×5 d or 2.5 mg of fondaparinux sodium qd×5 d.

Statistical analysis

Descriptive statistics (mean, SD, median, range, proportion) were used for initial analysis. Modified Student t test was used for comparison of continuous data, chi-square test was used for comparison of dichotomous data. Stepwise multiple logistic regression models were used to determine predictors of TRA-PCI failure. All analyses were performed with SPSS

Table 1. Baseline characteristics

	TRA-All (n = 1276)	TRA-PCI Success (n = 1162)	TRA-PCI Failure (n = 114)	*p* Value*
Age (years)	63.79±10.43	63.69±10.27	64.82±11.90	0.333
Age > 75 years	182 (14)	155 (13)	27 (24)	0.012
Female	262 (21)	217 (19)	45 (39)	0.000
Hypertension history	730 (57)	662 (57)	68 (60)	0.775
Diabetes history	384 (30)	352 (30)	32 (28)	0.716
Dyslipidemia	523 (41)	476 (41)	47 (41)	0.972
Renal insufficiency	100 (8)	88 (8)	12 (11)	0.306
PCI history	248 (19)	232 (20)	16 (14)	0.200
Smoking history	810 (63)	761 (65)	49 (43)	0.017
Indication for PCI				
Stable angina	701 (55)	637 (55)	64 (56)	0.884
UA/NSTEMI	76 (6)	69 (6)	7 (6)	0.935
STEMI	499 (39)	456 (39)	43 (38)	0.833

Values are n (%) or mean ± SD. *Compared with transradial approach TRA-PCI Success. NSTEMI = non-ST-segment elevation myocardial infarction; PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction; UA = unstable angina.

version 19.0. A probability value of < 0.05 was considered statistically significant.

Results

Patients' characteristics

A total of 1,276 patients who underwent TRA-PCI were retrospectively analyzed. Mean age was (63.79±10.43) (57~72) years, and two hundred sixty-two patients (21%) were women. TRA-PCI procedural failure was switched to TFA-PCI in 114 (8.9%) patients, including 45 women (39%) and 69 men (61%). Immediate crossover to TFA-PCI was employed in all TRA-PCI failures and allowed procedural failure completion of PCI in 5 (4%) patients with an overall success rate of > 99%.

The baseline characteristics of the study population are described in **Table 1**. The patients in the TRA-PCI failure group were significantly more likely to be women(19% *vs* 39%, P < 0.001), and more likely to be age > 75 years (13% *vs* 24%, P = 0.012) compared with TRA-PCI success group. They were balanced in hypertensive history, diabetes history, dyslipidemia, renal insufficiency, PCI history, and indication for PCI.

Besides, the PCI procedural characteristics of the study population are described in **Table 2**. The patients in the TRA-PCI failure group were significantly more likely to suffer from left main coronary disease (4% *vs* 8%, P = 0.035), more heparin dose (6569.19±1266.31 *vs* 6837.72±1352.64, P = 0.032), longer fluoroscopy time (38.50±18.19 *vs* 53.05±24.91, P < 0.001), and more possibly final PCI procedure failure (1% *vs* 4%, P = 0.024) compared with the TRA-PCI success group. However, there was no significantly difference among patients with intervened coronary artery, contrast volume, GP IIb/IIIa, and stents.

Related risk factors of TRA-PCI failure

The univariate predictors of TR-PCI failure included female sex (odds ratio: 2.84; 95% confidence interval: 1.897 to 4.252, P < 0.001), and age > 75 years (OR: 2.016; 95% CI: 1.268 to 3.206, P = 0.003) (**Table 3**). PCI history, and presentation with an acute coronary syndrome were not predictive of TRA-PCI failure. On multivariate analysis, female sex (OR: 2.634; 95% CI: 1.746 to 3.973, P < 0.001), and age > 75 years (OR: 2.032; 95% CI: 1.260 to 3.278, P = 0.004) were independent risk factors for TRA-PCI failure. Interestingly, smoking history was not a risk factor in TRA-PCI successful group by this analysis. Since more male and less female have smoking history, it maybe because more female were switch to TRA-PCI failure group by bivariate correlation analysis (*P = 0.013*).

Causes of TRA-PCI failure

The main causes of TRA-PCI failure were vascular anomaly in 54 patients (47%), unsuccessful radial artery puncture in 34 patients (30%), and

Table 2. PCI Procedural Characteristics

	TRA-All (n = 1276)	TRA-PCI Success (n= 1162)	TRA-PCI Failure (n = 114)	*p* Value*
Vessel disease				
Single angiopathy	323 (25)	293 (25)	30 (26)	0.843
Multiple angiopathy	953 (75)	869 (75)	84 (74)	0.922
Left main coronary disease	51 (4)	42 (4)	9 (8)	0.035
Intervened coronary artery				
LAD	750 (59)	679 (58)	71 (62)	0.688
LCX	308 (24)	282 (24)	26 (23)	0.785
RCA	422 (33)	385 (33)	37 (32)	0.917
Heparin dose (U)	6593±1276	6569±1266	6837±1352	0.032
Fluoroscopy time (min)	39.80±13.32	38.50±18.19	53.05±24.91	0.000
Contrast volume (ml)	106.00±34.69	105.48±1.02	111.32±3.23	0.087
GP IIb/IIIa	172 (13)	163 (14)	9 (8)	0.067
Stent/patient	1.53±0.77	1.53±0.76	1.54±0.85	0.847
Procedural failure	19 (1)	14 (1)	5 (4)	0.024

Values are n (%) or mean ± SD. *Compared with transradial approach TRA-PCI Success. LAD = left anterior descending. LCX = left circumflex. RCA = right coronary artery.

Table 3. Multivariate predictors of TRA-PCI failure

	B Value	*p* Value	OR Value	95% C.I.
Female	0.969	0.000	2.634	1.746~3.973
Smoking history	-0.884	0.000	0.413	0.278~0.614
Age > 75 years	0.705	0.004	2.032	1.260~3.278

Table 4. Causes of TRA-PCI failure (n = 98)

Cause	n	Ratio (%)
Inadequate arterial puncture	34	30
Radial/Brachial artery spasm	11	10
Radial/Brachial artery stenosis	5	4
Radial/Brachial artery tortuosity	20	18
Subclavian tortuosity	6	5
Truncus brachiocephalicus tortuosity	7	6
Aortic tortuosity	5	4%
The causes of guide catheter or guide wire	26	23

with TRA. The failure of TRA-PCI was due to unsuccessful arterial puncture in 34 (30%) patients in whom a radial sheath could not be placed after initial clinical assessment suggested suitability for TRA-PCI.

Discussion

In this multivariate analysis of Chaoshan Chinese patients post TRA-PCI procedure, we found that female and age > 75 years were independent predictors of TRA-PCI failure. The patients in the TRA-PCI failure group were more likely to suffer from left main coronary disease. The common causes of TRA-PCI failure were vascular anomaly, unsuccessful radial artery puncture, and the causes of guide catheter and guide wire.

the causes of guide catheter and guide wire in 26 (23%) patients (**Table 4**). The guide catheter could not be advanced to the ascending aorta due to radial artery or brachial artery spasm impeding catheter manipulation or causing significant patient discomfort in 11 (10%) patients, radial artery or brachial artery stenosis in 5 (4%) patients, and vascular tortuosity in 38 (33%) patients. The TRA-PCI failure in these patients was attributed to calcification, tortuosity, and other features of the coronary anatomy that prevented successful delivery of stents and balloons to the target coronary segment

The findings from our retrospective analysis show that TRA-PCI can be performed with a low failure rate (8.9%) in a contemporary practice by low-to-intermediate volume TRA operators with standard radial sheaths and traditional TFA guide catheters. In patients with failed TRA, PCI was successfully completed in a majority of patients (96%) by switching to TF during the same procedure. In a large meta-analysis of randomized trials of radial versus femoral access, it was demonstrated a significantly higher rate of access site crossover with radial access (5.9%) [4]. It was representing only 38%

of total PCI volume showed a TRA-PCI crossover failure rate of 4.7% in 2,100 patients undergoing TRA-PCI over a 4-year period, where low-to-intermediate volume operators performed TRA-PCI in selected patients [4]. And it was reported failure rate of 4.9% in a series of 10,676 patients who underwent TRA-PCI [12]. Our failure rate was slightly higher than the above studies, but in general TRA-PCI was performed with a low failure rate.

In our retrospective multivariate analysis, female sex, and age > 75 years were independent risk factors of TRA-PCI failure. Age > 75 years is an independent predictor of TRA-PCI failure in Chaoshan population, which was consistent with abroad study [13]. It was also identified that prior coronary artery bypass graft surgery and short stature were independent predictors of TRA-PCI failure, but which was not proved in our study. Elderly persons constitute a growing segment of the patient population undergoing PCI and are at higher risk of periprocedural complications compared with youngers. The challenges of TRA-PCI in elderly patients include advanced vascular disease with an accompanying increased tortuosity of subclavian artery and aortic arch, aortic root dilation, calcification, and diffuse atherosclerosis of both great vessels and the coronary arteries who might produce complications in catheter manipulation and delivery of balloons and stents in elderly patients. The decrease in vascular complications with TRA needs to be carefully balanced against increased TRA-PCI failure rate, higher radiation exposure, and greater contrast volume in this high-risk population [14].

It was reported that female sex, previous CABG, and cardiogenic shock were independent predictors of TRA-PCI failure, in which the factor of female sex agrees with our retrospective analysis [15]. Furthermore, a novel simple clinical risk score was developed to stratify patients, and it can predict radial approach failure rates between 2% and 80% in contemporary PCI practice. A number of studies have shown a poorer outcome in women with coronary artery disease undergoing percutaneous coronary intervention. There can be several reasons that explain the findings: more advanced age, higher percentage of diabetes, and other angiographic factors such as vessel size, smaller in the female population [13]. The radial artery diameter is usually 2.5 to 3.0 mm at the level of the wrist, however, this is smaller than that in women. Moreover, female sex, diabetes, and low body mass index are independent predictors of radial artery spasm, which in turn may contribute to TRA-PCI failure [16]. Our results may make little contribution to the predictor research of TRA-PCI failure for range of China.

Our retrospective analysis found that TRA-PCI failure group was more possibly to exit left main coronary disease, more heparin dose, longer fluoroscopy time, and suffer from PCI procedure failure compared with the TRA-PCI success group. The results emphasized that patients of TRA-PCI failure were more likely to have left main coronary disease. For the patients with TRA-PCI failure, the risk factors were higher heparin dose and longer fluoroscopy time, which study was consistent with other report [17]. But we did not find that TRA-PCI failure group need more contrast volume and the number of stents. However, it was found that crossover TRA-PCI failure group (due to inability to complete the PCI procedure via TRA, requiring access site crossover to TFA) was longer fluoroscopy time and lower procedure success rate, and contrast volume is not significantly different [18]. These results further suggest the risk of TRA-PCI failure, not just for the surgery itself or hemorrhage complications and maybe influence the prognosis of patients.

Despite lower rates of bleeding and vascular complications as compared to TFA-PCI, the adoption of TRA-PCI has been relatively slow in part due to frustration from operator failure during the learning curve. We should understand the causes of TRA-PCI failure to reduce failure rates. In our retrospective analysis, we found that the causes of TRA-PCI failure included: vascular anomaly (radial artery or brachial artery spasm or stenosis, and vascular tortuosity (include radial/brachial artery, subclavian artery, truncus brachiocephalicus, aortic), unsuccessful radial artery puncture, and the causes of guide catheter and guide wire, which is consistent with the abroad studies [10, 11, 15]. Our results showed that abnormal vascular anatomy was an important cause of TRA-PCI failure. Radial artery anomalies were relatively common and a cause of transradial procedure failure even for experienced radial operators [16], Anatomical challenges of subclavian,

innominate, and aortic arch regions also play an important role in TRA-PCI failure. Using a simple, conceptual, framework to classify the anatomical or functional problem and then applying a logical approach to these challenges could facilitate management and augment operator success rates for TRA-PCI [17]. In addition, our results showed that the radial artery puncture failure rate was high. It was reported that ultrasonographically guided radial artery puncture was able to reduce the radial artery puncture failure rate [18], and which is an easy way to improve the success rate of TRA-PCI. Moreover, TRA-PCI success depends on the operator's experience [15]. The present findings have implications both for PCI operators looking to expand their skills and for defining standards for training.

This local retrospective analysis just includes the patients who underwent TRA-PCI in the First Affiliated Hospital of Shantou university medical college. Besides, height and body mass index were not analyzed in the history information. More information and area could be explored possible related factors in the future study.

Conclusions

Female and age > 75 years are independent risk factors of TRA-PCI failure in Chaoshan area people. The patients with failed TRA maybe possibly to suffer from left main coronary disease. The causes of TRA-PCI failure included vascular abnormalities etc. Appropriate patient selection and careful risk assessment are needed to maximize benefits offered by TRA-PCI.

Disclosure of conflict of interest

None.

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