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Transradial Versus Transfemoral Arterial Access During Percutaneous Coronary Intervention in Acute Coronary Syndromes: A Five Year Retrospective Analysis From a Large Tertiary Care Cardiac Centre of North India

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Abstract

Background: Transfemoral arterial approach (TFA) is still the most common approach used in many countries for percutaneous coronary intervention(PCI). Transradial arterial access (TRA) is increasingly gaining acceptance globally for PCI. Acccess site for PCI are important considerations especially for high risk and acute coronary syndrome (ACS) patients in whom the negative implications of major bleeding are even greater. *Aims and objective:* Our study comparedthetransradial and transfemoral artery approach for PCI in ACS patients in a north Indian population. *Material & Methods:* A five year retrospective data (April 2013- March 2018) of total patients of ACS including ST elevation myocardial infraction (STEMI) and Non ST elevation ACS (NSTEACS), who underwent PCI was retrieved from a registered and computerized database. The patients were divided into two groups depending upon transradial and transfemoral artery approach and compared for the various demographic and clinical features, risk factors profile, vascular access, procedural details and in hospital outcomes. *Results:* 1284 patients of ACS underwent percutaneous coronary interventions at our center during this five year period. 79.9% were male and 21.1% were female. 420 patients (32.7%) underwent PCI through the transfemoral route and 864 (67.3%) patients underwent PCI through the transradial route. The mean fluoroscopy time was significantly more prolonged in the TRA group (14.83±9.24 mins) than TFA group (13.2±7.42 mins, $p<0.001$). Access site related major complications, major bleeding and total duration of hospital stay were significantly ($p<0.001$) more in the TFA group as compared to TRA group. There was no significant difference in the rate inhospital mortality (0.47% vs 0.46%, $p=0.30$) between two groups. The rate of TIA/ischemic stroke was similar in TFA and TRA groups (0.23% vs 0.34% respectively, $p=0.07$). *Conclusions:* The transradial approach for PCI in ACS patients is safe and effective approach. The rates of major access site complications are more in transfemoral approach with lesser patient comfort than in transradial approach.

Keywords: Transfemoral Approach (TFA); Transradial Approach (TRA); Acute Coronary Syndrome (ACS); Percutaneous Coronary Intervention (PCI).

Introduction

Percutaneous coronary intervention (PCI) is an important part of management of patients with ACS. PCI along with appropriate pharmacological strategies has been shown to reduce morbidity and mortality in ACS [1]. Continuous refinement of technol-ogies and wider application of newer antithrombotic agents has improved the results of PCI with less is-chemic complications [2]. In the current era, transfemoral approach (TFA) is the most common access for PCI in many countries [3]. TFA is considered as a classical approach over transradial due to the unlimited repe-tition of puncturing, easy access, less radiation time, and less contrast. During the last two

decades, transradial approach (TRA) has gained acceptance as a valid alternative to TFA, because of rapid recovery and earlier ambulation, better patient comfort, shorter hospital stay and possibly reduced bleeding risk and hematoma formation [4].The vascular access site complications has been shown to occur in <1% of transradial procedures, which on the contrary occur in about 3% to 7% of patients undergoing procedures through the femoral route.

The patients with ACS usually require aggressive anticoagulation and potent antiplatelet treatment including adjunct use of glycoprotein IIb/IIIa inhibitors and hence, are especially at risk for access site related bleeding complications [5]. Bleeding complications and the consequent need for blood transfusion are independent predictors of survival in acute coronary syndromes and its effect on morbidity and mortality has been demonstrated in many studies [6-8].

Transradial approach has been demonstrated to be safe and efficacious alternative to transfemoral approach in elective coronary intervention procedures in various studies with less bleeding complications and early ambulation [9-11]. The safety of transradial procedures is mainly conferred by the favourable anatomic relations of the radial artery to adjacent structures and its superficial course with ease of hemostasis and minimal chances of limb ischemia due to collateral ulnar artery supply. The main disadvantage of TRA reported from earlier studies is high incidence of procedural failure leading to crossover to TFA however, recent studies have demonstrated similar procedural success between TRA and TFA even in complex group of PCI patients [12-13].

Material & Methods

Study Population

We collected the data of 1284 patients of acute coronary syndromes (Including ST elevation MI, Non ST elevation MI and unstable angina)who underwent percutaneous coronary angioplasty from April 2013 to March 2018 at our centre. Out of the total 3647 PCI performed during this period, 1284 PCI were done in cases of acute coronary syndrome. Retrospective data of these patients was collected from the clinical case records and procedure related details were retrieved from the registered and computerized database of the catheterization laboratory. The patients were divided into two groups those who underwent PCI via transradialapproach (TRA) and those who under went PCI via transfemoral approach were(TFA).

Our centre has multiple operators and choice of PCI access site or crossover to another access site (in case first access fails) is based on the discretion and preference of the operator and appropriateness of the radial or femoral artery pulsations.

Procedural details

Radial and femoral arterial access were gained using standard protocols. For diagnostic and therapeutic purposes, 6 Fr radial sheaths and 6/7 Fr femoral sheath were used. Anticoagulation after sheath insertion was obtained using unfractionated heparin according to standard guidelines with target activated clotting time of 200-300 secs. All patients were preloaded with adequate dual antiplatelet drugs before PCI and these were continued after procedure according to the guidelines. The choice of P2Y12 inhibitor was also based on the discretion of the physician. The patients also received adjunctive GP IIb/IIIa inhibitors during and after PCI in most of the cases. Approach cross-over occurred when the initial approach failed during coronary angiography or PCI, such as failed puncture, tortuous road, and difficult guiding catheter engagement or manipulation and failed PCI due to insufficient backup of guiding catheter. TIMI grade 3 coronary flow in the treated vessel with a residual stenosis < 20% was considered as successful PCI.

Hemostasis after transradial PCI and removal of sheath was achieved using transradial band application which was gradual deflated and removed when ACT of <180 secs. was achieved. In case of transfemoral PCI, hemostasis was achieved by sheath removal when ACT was below 180 secs.and bandage application with additional manual compression. Access sites and distal pulses were routinely evaluated immediately after procedure, next day after procedure and before discharge.

Study Variables

The data was analysed for clinical and demographic characteristics of the patientsand the presence or absence of various cardiovascular risk factors in the two (TFA & TRA) groups.

The percentage of STEMI, NSTEMI and unstable angina as the etiology of ACS were compared.

Various PCI and access site related variables like Successful vascular access, coronary cannulation, success rate of PCI, entry site complications, asymptomatic loss of radial pulsations, contrast dose, procedural and fluoroscopy times, periprocedural

cerebrovascular accidents (CVAs), length of hospital stay, major bleedingand inhospital mortality were compared between the tranfemoral and transradial group. Major bleeding was defined as one of the following: fatal retroperitoneal bleeding, intracranial hemorrhage or bleeding associated with a ≥ 3g/dLhemoglobin drop or requiring transfusion or requiring surgery.

The access site complications like access failure, local site hematomas, loss of distal or radial pulse, cross over to another access site, pseudoaneurysm formation, arteriovenous fistula, retroperitoneal hematoma, limb ischemia requiring surgery, were also compared between the two groups.

Statistical analysis

The data were expressed as absolute numbers, percentage and mean±standard deviation. Continuous data were analysed using the t-test and categor-ical data were analyzed using the chi-squaretest or fisher's exact test. Statistical analysis was performed using SPSS software, version 17.0 (SPSS, Inc., Chicago, Illinois). Statistical significance was defined as $P < 0.05$.

Results

Baseline clinical characteristics

A total of 1284 patients of ACS underwent PCI at our centre from April 2013 to March 2018 that represented 35.2% of the total PCI (n=3647) performed during this period. Among these ACS patients 420 (32.7%) underwent PCI through the transfemoral route and 864 (67.3%) patients underwent PCI through the transradial route (Figure 1). The baseline features of these patients are provided in Table1. There were no statistically significantdifferences between the transfemoral (TFA) and transradial (TRA) groups in terms of mean age, male:female ratio, body mass index and cardiovascular risk factors (hyper-tension, diabetes, dyslipidemia, family history of CAD. The proportion of patients who presented as STEMI, NSTEMI and unstable angina was similar in both the groups and mean LV ejection fraction was also similar.

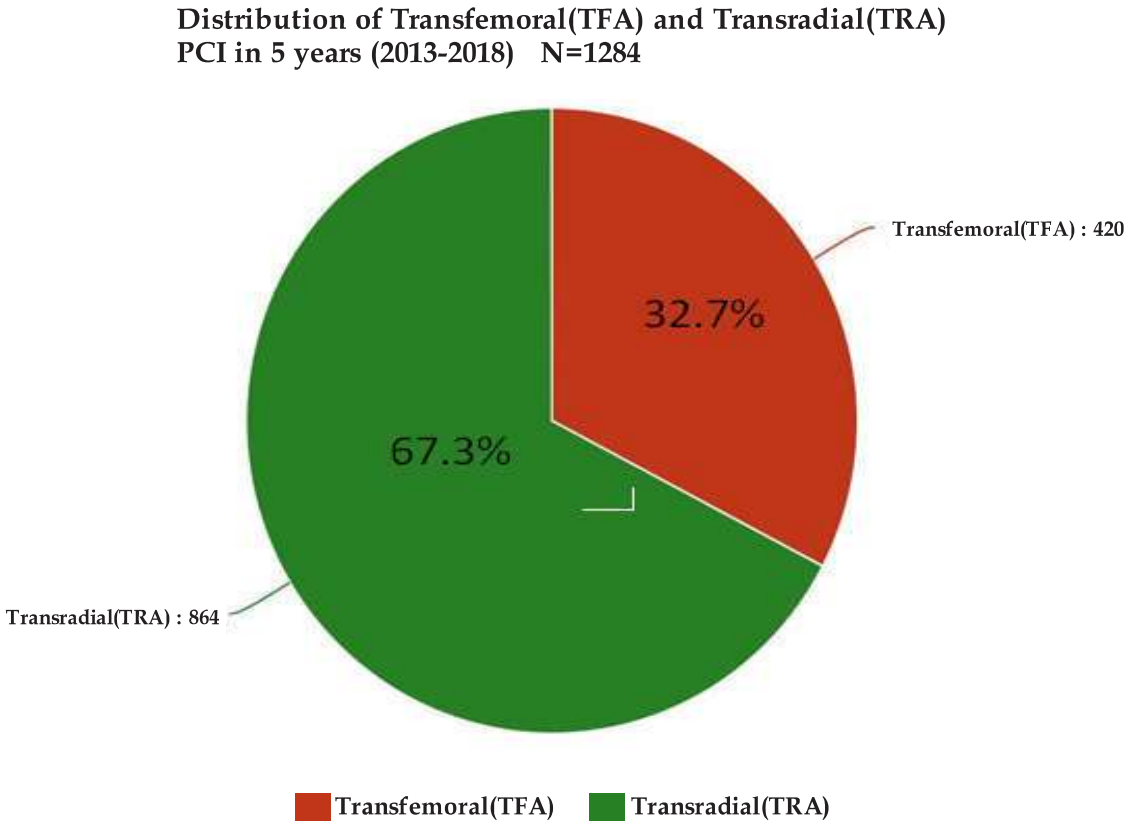

Fig. 1: Percentage of TransradialVs.Transfemoral PCI.

Table 1: Baseline Characteristics of the Study Participants (Total n=1284).

	Transfemoralgroup(TFA) n=420(32.7%)	Transradialgroup (TRA)n = 864(67.3%)	P Value
Mean age	56.7 ± 6.7	54.1± 8.2	0.19
Male (79.9%)	291(69.2%)	592 (68.5%)	NS
Female(21.1%)	129 (29.8%)	272 (31.5%)	NS
Diabetes	128(30.5%)	257 (29.8%)	0.09
Hypertension	179 (42.6%)	372 (43.1%)	0.23
Current smoker	103(24.6%)	175 (20.2%)	<0.001
Tobacco chewer	144(34.3%)	300 (34.8%)	0.21
BMI(Body mass index)	23.8 ± 3.2	24.6 ± 4.8	0.06
Family History of CAD	61 (14.4%)	126 (14.6%)	0.21
Dyslipidemia	113(26.8%)	235(27.2%)	0.33
ST elevation MI n=414(32.3%)	135(32.5%)	279(67.5%)	NS
Non STEMI n=594(46.2%)	183(30.7%)	411(69.3%)	NS
Unstable angina n=276(21.5%)	88(31.8%)	188(68.2%)	NS
LV EF %	54.2±11.6	53.8±12.6	0.56
Kilip class(II-III)	02(0.47%)	04(0.46%)	0.30

Table 2: Procedural characteristics of the Percutaneous coronary intervention (Total n=1284).

	Transfemoralgroup (TFA) n=420(32.7%)	Transradialgroup (TRA)n = 864(67.3%)	P Value
Mean fluoroscopy time (minutes)	13.2 ± 7.42	14.83± 9.24	< 0.001
Contrast dose(ml)	121 ± 26	124 ± 22	0.03
GPIIb/IIIa use	375 (89.3%)	783 (90.6%)	0.25
Success rate of PCI	99.4%	99.3%	0.06
Complete revascularization in multivessel PCI	99.2%	98.9%	0.16
Access site success	99.6%	97.4%	<0.001
Failed access	02(0.47%)	22 (2.6%)	<0.001
Crossover to another site	01 (0.23%)	21(2.43%)	<0.001
Mean hospital stay (days)	2.4 ± 1.8	1.4 ± 2.2	<0.001
In hospital mortality	02(0.47%)	04(0.46%)	0.30
CVA(TIA/Infarct/bleed)	01(0.23%)	03(0.34%)	0.07
Major bleeding	03(0.71%)	02(0.23%)	<0.001

Procedural characteristics

The procedural characteristics are summarized in table 2. The access site success was more commonly achieved in patients in the TFA group(99.6%)than patients in the transradial group (97.4%) (p<0.001). The rate of Successful PCI was similar in TFA (99.4%) and TRA group (99.3%)(p=0.06). Failed access was seen significantly more in the transradialgroup(2.6%) as compared to 02 (0.47%)(p<0.001) patients in the TFA group. The most patients in the failed transradial group underwent procedure by the transfemoral route except for two patients which underwent procedure by the contralateral transradial route. 01 patient (0.23%) in the TFA group underwent procedure by the contralateral transfemoral route. The rate of complete revascularisation in multivessel PCI was similar in both the groups (99.2% in TFA vs 98.9% in TRA, P=0.16). The mean fluoroscopy time was significantly more prolonged in the TRA group (14.83 ±9.24mins) than TFA group (13.2±7.42mins, p<0.001). The dose of contrast used during PCI was slightly more in TRA group (124±22ml) than TFA group(121±26ml, p=0.03). The duration of hospital stay was significantly more in the TFA group (2.4± 1.8days) than TRA group (1.4±2.2 days, p<0.001).The patients in the TRA group had early mobilisation and reduced total cost due to lesser hospital stay. GPIIb/IIIa inhibitors use was similar in both the groups (around 90%). There was no significant difference in the rate inhospital mortality between two groups. The rate of TIA/ ischemic stroke was similar in TFA and TRA groups (0.23% vs 0.34% respectively, p=0.07) and most of them recovered neurologically during hospital stay. One patient in the TRA group had large intracranial haemorrhage for which open surgical decompression was done.

The most of the access site related complications were seen more commonly in the TFA group (Table 3, Figure 2). Radial artery spasms during PCI were usually non procedure limiting however, in a significant percentage of patients (1.8%) shifting to another access site was required. The loss of distal pulses were seen in 4 patients

(0.95%) in the TFA group as compared to loss of radial pulse in 18 patients (2.0%) (p<0.001) in the TRA group. The local site major hematoma was significantly more common in the TFA group (1.4%) as compared to TRA group (0.23%) (p<0.001) and 02 patients (0.47%) in the TFA group required blood transfusions and prolonged manual compression. The pseudoaneu-rysm was seen in 01 patient (0.23%) in the TFA group and retroperitoneal hematoma(non fatal) was also seen in 01 patient (0.23%) in the TFA group. Major bleeding including entry site and other site bleeding (gastrointestinal, intracranial & urinary) was seen in 03 (0.71%) patients in the TFA group and 02 patients (0.23%) in the TRA group(p<0.001).01 patient (0.23%) in the TFA group required surgical intervention for the limb ischemia using embolectomy. None of the patients in the TRA group had severe upper limb ischemia.

The vesselwise distribution of the PCI is shown in Table 4. Single vessel PCI was the most common interventional procedure (64.8%) with Left anterior descending artery (LAD) was tackled in most (60.2%) of the cases. The double vessel PCI and triple vessel PCI were done in 30.3% and 3.9% of the cases respectively and the 08 patients (0.6%) underwent unprotected left main PCI. The rate of TFA and TRA approach was similar in all PCI groups as compared to general trend. The 05 patients (0.38%) underwent post bypass graft PCI and all were done through the transfemoral route. The yearwise trend of transfemoraland transradial PCI showed the significant increase in use of transradial approach over period of five years which is depicted in figure-3. In the first two years the majority of PCI were done through the TFA route and in the last two years most of the procedures were done through the transradial route. In the last year of the study 81.4% of the PCI were done through the TRA route as compared to

Table 3: Access site complications in Percutaneous coronary intervention (Total n=1284).

	Transfemoralgroup (TFA) n=420(32.7%)	Transradialgroup (TRA)n = 864(67.3%)	P Value
Local site hematoma	06(1.4%)	02(0.23%)	< 0.001
Pseudoaneurysm	01 (0.23%)	0	-
Distal artery occlusion/Loss of distal pulse	04 (0.95%)	18 (2.0%)	<0.001
Retroperitoneal hematoma	01(0.23%)	0	-
Arteriovenous fistula	0	0	-
Surgical intervention for limb ischemia	01(0.23%)	0	-

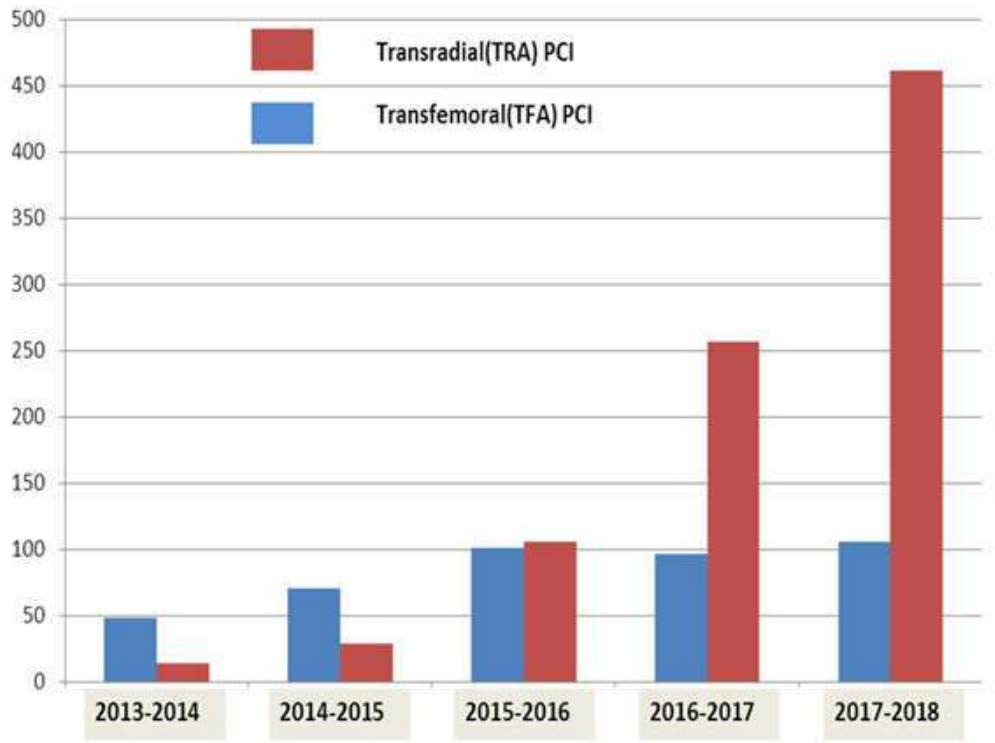

Fig. 2: Yearwise distribution of number of Transradial and Transfemoral procedures.

Table 4: Characteristics of the Percutaneous coronary intervention according to vessel involved (Total n=1284).

	Transfemoralgroup (TFA) n=420(32.7%)	Transradialgroup (TRA)n = 864(67.3%)
Single vessel PCI(n=832)64.8%	256(30.8%)	576(69.2%)
Double vessel PCI(n=389)30.3%	124(31.9%)	265(68.1%)
Triple vessel PCI(n=50)3.9%	18 (32%)	32 (68%)
Left main PCI(n=8)0.6%	05(62.5%)	03(37.5%)
Graft PCI(n=05)0.38%	05 (100%)	0
Bifurcation PCI(n=15)1.2%	10(70.7%)	05(29.3%)
LAD artery(n=773)60.2%	270(34.8%)	503(65.2%)
RCA artery(n=447)34.8%	160 (35.7%)	287(64.3%)
LCX artery(n=316)24.6%	104(32.8%)	212(67.2%)
Ramus artery(n=36)2.8%	14(35.1%)	22(64.9%)

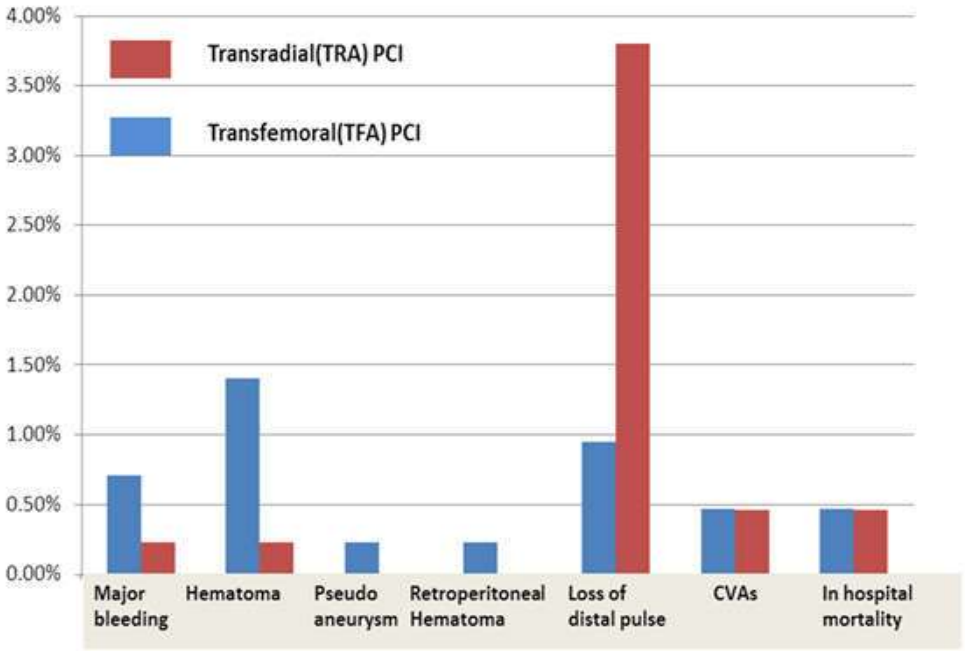

Fig. 3: Access site and other complications in TransradialVs.Transfemoral PCI.

18.6% by the TFA route. This can be explained by the increasing expertise and learning curve of the operators.

Discussion

Transfemoral approach still remains the most commonly adopted route for PCI in many centres worldwide. The use of transradial route for PCI has increased dramatically in the last two decades,since the first report of transradial PCI in 1992 by Kiemeneij [14]. Transradial PCI offers the potential benefits like ease of in-laboratory sheath removal, early ambulation, and facilitated discharge as well as cost savings. Furthermore in transradial PCI, the ability to identify and control access site hemorrhage promptly is facilitated and is especially relevant with the substantial anticoagulation, antiplatelet regimens and adjunctive GPIIb/IIIainhibitors used during and after PCI, which potentially benefits patients at high risk of thrombosis, such as, acute coronary syndrome (ACS).

The successful access site entry is more commonly seen in the TFA group than the TRA group and the failure rates can be more in diabetics and female subjects who have relatively smaller radial arteries [15]. In our study, the access site success was significantly more commonin patients in the TFA group(99.99%) than patients in the TRA group (97.4%). Access failure was seen in 2.6% patients in the TRA group and various factors like

radial artery puncture failure, severe radial spasm, angulation and tortuosity of the innominate artery, dilated ascending aortaand arterialusoria contributed to failed radial access. In a ramdomized study of comparison of TFA and TRA approach, successful catheterization was achieved in 96.5% of 512 patients in the transradial group and in 99.8% of the 512 patients in the transfemoral group (p=0.10) [16]. Despite the higher incidence of radial artery spasms and subsequent difficult coronary cannulation and guidecatheter support encountered during PCI, the transradial approach still offers the high procedural success rate and PCI outcomes similar to those of transfemoral PCI albeit, at the cost of slightly increased fluorotime and length of procedure. In our study the mean fluoro time was significantly increased in the TRA group as compared to the TFA group with marginally increased contrast dose in the TRA group. The PCI success rates in our study were similar in both TFA and TRA groups and the same observation was seen in other large studies [16]. The rate of CVAs and in hospital mortality were similar in both TRA and TFA groups. Two major randomized trials (RIVAL [17] & MATRIX [18]) in patients with ACS and one large rando-mized trial in STEMI patients (RIFLE-STEACS [19]) comparing TRA and TFA approach have been done. In the RIVAL trial, the rate of death, myocardial in-farction, or stroke at 30 days was 112 (3·2%) of 3507 patients in the radial group compared with 114 (3·2%) of 3514 in the femoral group (p=0·90). The MATRIX trial showed that in 8404 patients with acute coronary syndrome, with or without ST-segment elevation, randomized to radial (4197) or femoral (4207) access for coronary angiography and percutaneous coronary intervention, 369 (8·8%) patients with radial access had major adverse cardiovascular events, compared with 429 (10·3%) patients with femoral access (p=0·0307).and all-cause mortality (1·6% vs 2·2%, p=0·045) was significantly lower in radial group. In the RIFLE-STEACS trial radial access was associated with significantly lower rates of cardiac mortality (5.2% vs. 9.2%, p = 0.020), and shorter hospital stay (5 days first to third quartile range, 4 to 7 days] vs. 6 [range, 5 to 8 days]; p = 0.03). A systematic review and meta-analysis of TFA vs TRA approach in 9726 STEMI patients comprsing 16 trials showed that all-cause mortality, major bleeding, access site bleeding, major adverse cardiovascular events, and length of hospital stay were significantly lower with the transradial compared with the transfemoral approach however, the rates of stroke were numerically greater with transradial approach but did not achieve statistical significance [20].

Major bleeding is a common non-cardiac complication of PCI and at 30 days, approximately 5% of patients with ACS experience major bleeding events [21]. Up to 80% of all major bleeding events associated with PCI may be access-site related and correlated with this, is a step-wise increase in 30-day mortality as the severity of bleeding increases from mild to moderate to severe [22]. The relationship between major bleeding after PCI and death is likely to be multifactorial. Major bleeding could directly increase the risk of death by causing hemodynamic compromise and could lead interventionists to discontinue anti-thrombotic agents. Bleeding also may curtail oxygen delivery to the myocardium and anaemia-induced erythropoietin release may promote a systemic prothrombotic state.

In the RIVAL trial the rate of non-CABG-related major bleeding at 30 days was 24 (0.7%) of 3507 patients in the radial group compared with 33 (0.9%) of 3514 patients in the femoral group (p=0.23). In the MATRIX trial the rates of major bleeding unrelated to coronary artery bypass graft surgery were significant more in the TFA group than TRA group (2.3% vs 1.6%, p=0.013). The major bleeds in RIFLE-STEACS trialwere significantly lower in the TRA than TFA group (7.8% vs. 12.2%, p = 0.026).

The femoral artery is a large, high pressure vessel and achieving hemostasis post-procedure can be challenging and is associated with major bleeding events and other vascular complications like hematoma and pseudoaneurysm formation. In the RIVAL trial, at 30 days, 42 of 3507 patients in the radial group had large haematoma compared with 106 of 3514 in the femoral group (p<0·0001). Pseudoaneurysm needing closure occurred in seven of 3507 patients in the radial group compared with 23 of 3514 in the femoral group (p=0·006). In our study the rate of pseudoaneurysm and major hematoma formation were significantly more in the TFA group but these complications settled with manual compression without having any surgical intervention.Brueck et al[16] has shown that despite use of vascular closure devices for transfemoral intervention vascular complications remain higher in the TFA group (3.7%) as compared to TRA group (0.53%)(p<0.001).

The asymptomatic radial artery occlusion (RAO) is an underestimated complication of the transradial PCI. RAO eliminates the ability to use the radial artery as an access in the future. A number of factors that contribute to the occurrence of RAO have been identified [23], such as the size of the sheath and the catheter, diameter ratio of the sheath to the diameter of the radial artery, insufficient

anticoagulation and, above all, the way of obtaining hemostasis: the duration of artery compression after sheath removal and the preservation of artery patency during compression (known as patent hemostasis). RAOs were seen in 18 (2.0%) patients in the TRA group in our study, out of which 4 (0.46%) patients required subsequent transfemoral approach for further intervention. All TRA patients in our study underwent patency documented hemostasis using transradial band which has been shown to decrease RAOs signifi-cantly than conventional hemostasis [24].

Our study showed gradual increase in transradial PCI over period of 5- years with major shift in complex and multivessel PCI to transradial route in the last two years of the study. This highlights the concept of learning curve that as operator transradial interven-tion (TRI) volume increases, higher risk patients are chosen for TRI. Despite this, operator proficiency improves with greater TRI experience, and safety is maintained [25].

Conclusion

The TRA approach for PCI in ACS patients is a safe and effective approach. The TFA approach is associated with more entry site complications as compared to the TRA approach although, procedure time and access site success rates are more with TFA approach. The duration of hospital stay and major bleeding rates are substantially reduced with transradial PCI with more patient comfort and lesser overall hospital cost. The higher rates of transradial PCI success is seen with increasing operator expertise.

Limitations

Our study is based on retrospective observational data collection with single centre experience thus findings should be interpreted accordingly. It is a nonrandomized study so selection bias can not be ruled out.

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