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Transradial Versus Transfemoral Coronary Intervention for Acute ST- Elevation Myocardial Infarction patients undergoing primary PCI

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Abstract

Background: Patients with ST-segment elevation myocardial infarction (STEMI) require an urgent revascularization strategy as well as aggressive antiplatelet and antithrombotic pharmacotherapy and thus are particularly susceptible to bleeding complications.This study aimed toassess and compare the feasibility, success and safety of transradial approach (TRA) versus transfemoral approach (TFA) in STEMI patients undergoing 1^{ry} PCI regarding clinical outcomes and vascular complications. **Patients and methods:**This randomized controlled study included 80 patients who were admitted to the National Heart Institute in the period between May 2015 to September 2017, because of ST-elevation myocardial infarction (STEMI) andwere planned for 1ry PCI. Patients were divided into two groups, each group included 40 patients. Group I; underwent tarnsradial PCI and Group II; underwent tarnsfemoral PCI. We compared between both groups as regards in hospital major bleeding & vascular complications and followed up for 3 months for (MACE). **Results:** The primary end points were statistically insignificant in both groups however large access site hematoma occurred in 3 patients in TFA group compared to none of patients in TRA group. Additionally, one case had gastrointestinal hemorrhage in TFA group compared to none of patients in TRA group. The secondary end points: major adverse cardiac events (MACE) during the in-hospital stay & 3 months follow up were statistically not significant in both groups. However, one case of mortality occurred in TFA group while no cases occurred in TRA group. The range of patients hospital stay was from 1 to 3 days with mean 2.1±0.38, while inTRAgroup.While itwas from 2 to 6 days with mean 3.9±1.0 in TFA group, and that was statistically highly significant (P 0.001).**Conclusions**:1ryPCI for STEMI can be performed via RA with DTBs clinically equivalent to those performed from FA after adequate experience and training.

Keywords:STEMI, Transfemoral, Transradial

INTRODUCTION:

A growing body of literature has shown that periprocedural bleeding is an independent predictor of adverse events including death following PCI. Thus, the term “bleeding avoidance strategies” has emerged reflecting that multiple factors have been associated with an increase in bleeding, and may have additive effects on this outcome. Although multiple factors contribute to bleeding after PCI, the access site (i.e., femoral or radial artery) has recently come under intense scrutiny as a source of potential bleeding, and by extension, a potential modifiable factor in an effort to reduce bleeding complications[(1)].

Patients with ST-segment elevation myocardial infarction (STEMI) require an urgent revascularization strategy as well as aggressive antiplatelet and antithrombotic pharmacotherapy and thus are particularly susceptible to bleeding complications. Trials of antithrombotic regimens designed to decrease bleeding complications during STEMI treatment have been shown to decrease mortality[(2)].

ST segment elevation myocardial infarction (STEMI) patients treated with primary percutaneous coronary intervention (PPCI) are particularly likely to benefit from the bleeding reduction of the radial approach as these patients have a greater risk of access site bleeding and other access-related complications given the emergent nature of the procedure and the need for aggressive antiplatelet and antithrombotic therapies. Another potential benefit of the radial approach is that it may allow higher doses of anticoagulants to be used for further ischaemic reduction while minimizing the penalty of increased bleeding. In addition, the use of the radial approach in STEMI patients has been associated with a significant reduction in major adverse cardiac events during follow-up[(3)].

The interest in the transradial approach is increasing due to decreased associated vascular complications, convenience for the patients, earlier discharge, shorter stay in the hospital and early ambulation. Not only is it a safer technique, but it is also characterized by its high success rate, close to

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90% in some populations. Vascular complications are lesser in the transradial approach because of favourable anatomy, smaller size of the sheaths used and rapid hemostasis. The main complications for the approach are smaller radial artery that may not be accessed successfully and arterial occlusion post procedure. Radial artery is smaller in the Asian populations compared to West[(4)].

The current STEMI guidelines of the European Society of Cardiology give a class IA recommendation for radial over femoral access for primary PCI if performed by an experienced radial operator[(5)].The aim of the present study was to assess and compare the feasibility, success and safety of transradial approach (TRA) versus transfemoral approach (TFA) in STEMI patients undergoing 1^{ry} PCI regarding clinical outcomes and vascular complications.

PATIENTS and METHODS:

A randomized controlled study was conducted on 80 patients with STEMI who had undergone primary PCI by using similar numbers of patients in the TRA and TFA group. 40 patients were randomly assigned to radial access (group I) (38 males, 2 females), ages (32 to 69) years old with mean age (52.8 ± 8.8) and 40 patients to femoral access (group II) (31 males, 9 females), ages (30 - 72) years old with mean age (53.6 ± 9.25) in the National Heart Institute in the period between May 2015 and September 2017.

Exclusion criteria were:patients in which coronary artery bypass graft surgery (CABG) was recommended & patients who had previous (CABG) surgery, patients with decompensated liver disease and chronic kidney disease, patients who received thrombolytic therapy in last 12 hours. Patients with STEMI complicated with cardiogenic shock, patients who presented lately (more than 12hrs after symptom onset) or who were off chest pain at presentation.

All patients in the study were subjected to full detailed history taking & clinical examination including: age, sex, risk factors (as DM, hypertension, smoking, family history, previous CABG, previous PCI),Killip classification, symptom onset to first balloon time, resting ECG to confirm STEMI, echocardiography to obtain systolic & diastolic functions and RWMAs during 1st day and 1month later, laboratory investigations: quantitative troponin, CBC, PT, PTT and INR were obtained before and after PCI, liver enzymes (ALT and AST), serum creatinine, complete lipid profile.

Diagnostic angiography and PCI were performed through either the femoral or radial artery after administration of thienopyridine loading dose (clopidogrel 600 mg), ASA loading dose 300 mg if not previously administrated, plus unfractionated heparin (70 to 100 U/kg) to maintain activated clotting time of > 250 seconds in patients during the procedure.

The choice of the access route was left to the discretion of the investigator.After the guidewire crossed the lesion, stenting was performed. For most procedures, baremetal stents were implanted. GP IIb/IIIa inhibitor was used at the discretion of individual operator. The occurrence of angiographic complications during PCI was recorded including: failed PCI such as wire or balloon passage failure, side branch occlusion, slow or no- reflow, major dissection, and distal embolization. Procedural success was defined as the achievement of a TIMI- 3 flow grade and residual stenosis <30% (by visual angiographic assessment). Procedure times were measured from the start of the puncture to the removal of the guiding catheters. Fluoroscopy times were measured automatically using fluoroscopes. After the procedure, all patients received life-long oral aspirin (100mg) and oral clopidogrel (75 mg/day) in addition to the other cardiovascular beneficial medications including β-blockers, renin angiotensin system inhibitors, and statins. After discharge, patients were encouraged to stay on the same medications as they received in the hospital.

Follow up:

The selected patients were followed up during in-hospital stay, 30 days and three months after primary PCI to determine major adverse cardiac events (MACE) (non-fatal myocardial infarction; recurrent ischemia; congestive heart failure; mortality) & periprocedural myocardial infarction.

Statistical analysis

The collected data was revised, coded, tabulated and introduced to a PC using Statistical package for Social Science (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp). Data was presented and suitable analysis was done according to the type of data obtained for each parameter. P value was set at P<0.01; Highly significant (HS).

RESULTS:

Figure 1; showed that the door to balloon time (DBT) in group I: its range was from 15 to 35 min with mean 24±5.9 minwhile in **group II:** the range was from 15 to 90 min. with mean 23±11.4. that was statistically insignificant (P 0.582).

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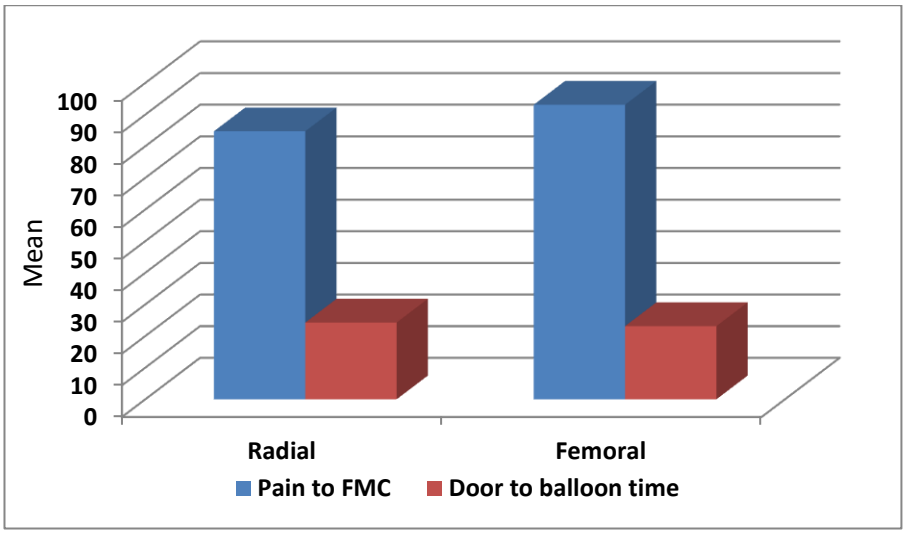

Figure (1): Comparison between two study groups as regard pain to (FMC) and (DBT).

Figure 2; Fluroscopy time in group I: the range was from 30 to 60 min. with mean 44±10.8mlwhile **in group II:** the range was from 25 to 80 min. with mean 39.5±11. that was statistically insignificant (P 0.246).

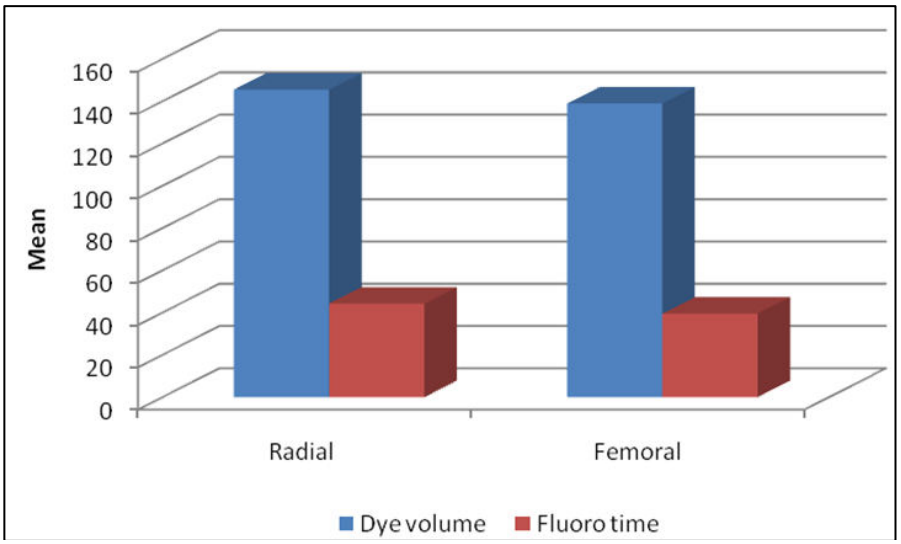

Figure (2): Combined bar chart showing dye volume and fluoroscopy time among study groups.

Table (1): Comparison between two study groups as regard bleeding and vascular complications

		Radial N (%)	Femoral N (%)	P	Sig
PCI access Hge (%)	No	40 (100.0)	40 (100.0)	NA	NA
	Yes	0 (0.0)	0 (0.0)		
PCI access Hematoma (%)	No	40 (100.0)	37 (92.5)	0.241**	NS
	Yes	0 (0.0)	3 (7.5)		
Non PCI access hematoma (%)	No	40 (100.0)	40 (100.0)	NA	NA
	Yes	0 (0.0)	0 (0.0)		
Non PCI access hge (%)	No	40 (100.0)	39 (97.5)	1.0**	NS
	Yes	0 (0.0)	1 (2.5)		
False aneurysm (%)	No	40 (100.0)	40 (100.0)	NA	NA
	Yes	0 (0.0)	0 (0.0)		
ICH (%)	No	40 (100.0)	40 (100.0)	NA	NA
	Yes	0 (0.0)	0 (0.0)		
IOH (%)	No	40 (100.0)	40 (100.0)	NA	NA
	Yes	0 (0.0)	0 (0.0)		
Retroperitoneal bleeding (%)	No	40 (100.0)	40 (100.0)	NA	NA
	Yes	0 (0.0)	0 (0.0)		

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Other sites (%)	No	40 (100.0)	39 (97.5)	1.0**	NS
	Yes	0 (0.0)	1 (2.5)		

**Fisher exact test

From table (1) it was found that **PCI access-site related hemorrhage** was absent in all patients in group I and in group II. **PCI access-site related hematoma; In group I:** it was absent in all patients (0%), while in **group II:** it was evident in 3 patients (7.5%); however, these differences did not reach statistical significance (p. 0241). **Non-PCI access-site related hemorrhage; In group I:** it was absent in all patients (0%), while in **group II:** it was evident in one patient (2.5%) due to gastrointestinal hemorrhage; however, the difference did not reach statistical significance (P 1.0). **Other complications; non-PCI access-site related hematoma, false aneurysm, intracranial bleeding, intraocular bleeding and retroperitoneal bleeding:** They were absent in all patients in group I and in group II(0%) figure 3.

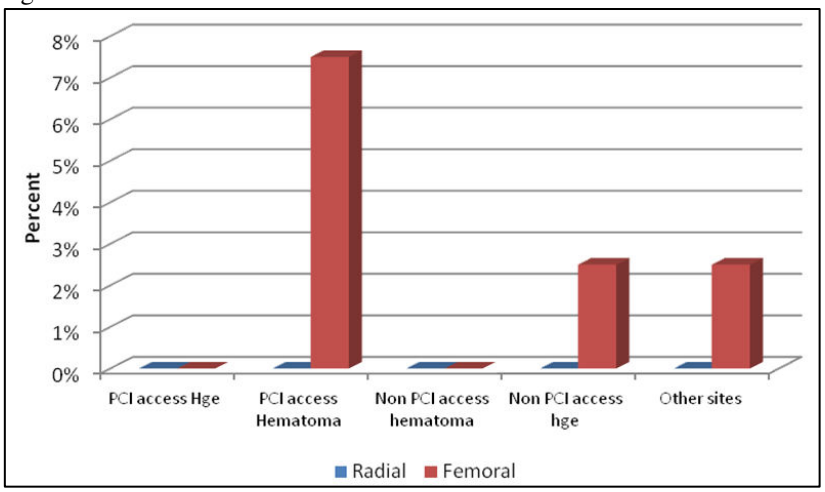

Figure (3): Combined bar chart showing vascular and bleeding complications among study groups.

Table (2): Comparison between two study groups as regard complications during in hospital stay & follow-up:

		Radial	**Femoral**	**P**	**Sig**
		Mean (SD)	**Mean (SD)**		
EF after 1 month		52.77 (4.78)	49.30 (9.75)	**0.046**‡	**S**
Troponin		1.90 (2.12)	7.22 (3.96)	**0.001**‡‡	**HS**
CKMB		60.38 (11.96)	79.30 (25.94)	**0.001**‡	**HS**
Hospital stay (Days)		2.10 (0.38)	3.92 (1.04)	**0.001**‡	**HS**
		N (%)	**N (%)**		
Death (%)	No	40 (100.0)	39 (97.5)	1.0**	NS
	Yes	0 (0.0)	1 (2.5)		
Stroke (%)	No	40 (100.0)	40 (100.0)	NA	NA
	Yes	0 (0.0)	0 (0.0)		
Emergency CABG (%)	No	40 (100.0)	40 (100.0)	NA	NA
	Yes	0 (0.0)	0 (0.0)		
Re infraction (%)	No	40 (100.0)	40 (100.0)	NA	NA
	Yes	0 (0.0)	0 (0.0)		
Stent thrombosis (%)	No	40 (100.0)	40 (100.0)	NA	NA
	Yes	0 (0.0)	0 (0.0)		
Re vascularization (%)	No	40 (100.0)	40 (100.0)	NA	NA
	Yes	0 (0.0)	0 (0.0)		
No reflow (%)	No	40 (100.0)	40 (100.0)	NA	NA
	Yes	0 (0.0)	0 (0.0)		

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Dissection (%)	No	40 (100.0)	40 (100.0)	NA	NA
	Yes	0 (0.0)	0 (0.0)		
Coronary perforation (%)	No	40 (100.0)	40 (100.0)	NA	NA
	Yes	0 (0.0)	0 (0.0)		
CIN (%)	No	40 (100.0)	38 (95.0)	0.494**	NS
	Yes	0 (0.0)	2 (5.0)		

‡Student t test ‡‡Mann Whitney test **Fisher exact test

Table (2) it was found that **Ejection fraction after 1 month; In group I** the range of EF% after one month was from 40 to 60% with mean 52.7±4.7while in **group II** the range of EF% after one month was from 50 to 60% with mean 49.3±9.7. That was statistically significant (P 0.046). **Peak quantitative troponin; In group I** the range of peak troponin was from 0.2 to 7.5ng/ml with mean 1.9±2.1while in **group II:** the range of peak troponin was from 0.30to 15ng/ml with mean 7.2±3.9, that was statistically highly significant (P 0.001).

Peak CK-MB; In group I: the range of peak CK-MB was from 40 to 90 ng/ml with mean 60.3±11.9**,** while in **group II:** the range of peak CK-MB was from 45 to 130 ng/ml with mean 79.3±25.9, that was statistically highly significant (P 0.001).

The hospital stay figure 4 in group I: the range of patients hospital stay was from 1to 3 days with mean 2.1±0.38, while in **group II:** the range of patients hospital stay was from 2 to 6days with mean 3.9±1.0, that was statistically highly significant (P 0.001).

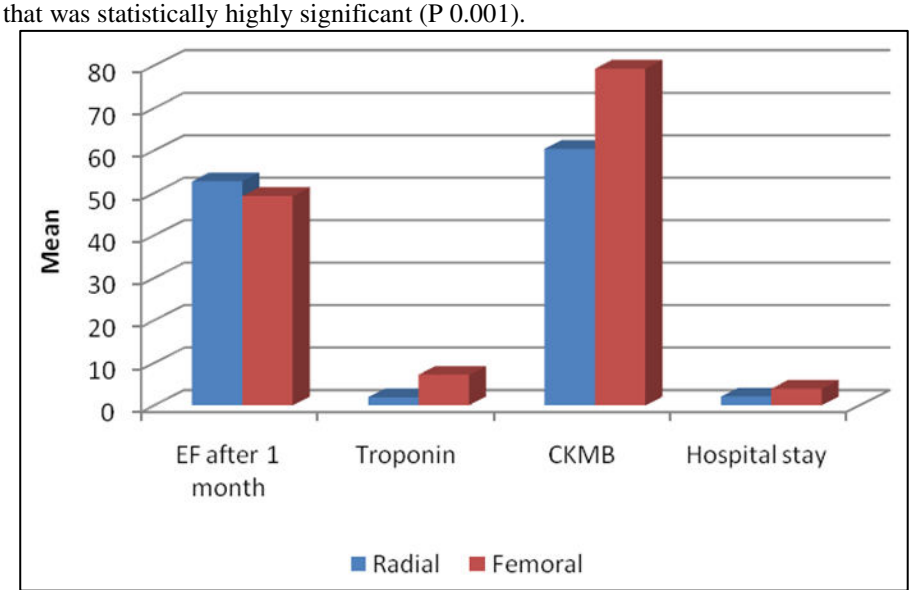

Figure (4): Combined bar chart showing the hospital stay and in hospital peak cardiac enzymes and EF after 1 month among study groups.

DISCUSSION:

In our study DTB time was statistically insignificant between both groups. This was in agreement with ***Romagnoli et al.***[6]who found DTBs were 53 min (31 to 91 min) for radial and 60 min (35 to 99 min) for femoral (p = 0.175). Thus, there was a small non-significant increase in DTB with the radial approach. This came also in agreement with ***Bernat et al.*** [7]who found DTBs were very low and similar in both RA and FA groups,32 ± 11 min and 31±11 min, respectively (p =0.31).

In our study the fluoroscopy times were statistically insignificant between both groups, this was not in agreement with ***Jolly et al.*** [8] who found that overall fluoroscopy times were slightly longer for radial than femoral 9.3 min versus 8.0 min but these differences were substantially mitigated by high-volume operators and centers. Similarly, the data from ***Bernat et al.*** [7]showed slightly higher fluoroscopy times for radial compared with femoral cases, but the difference was seen almost exclusively among low volume centers. These data strongly support the concept that experience with radial approach can eliminate differences in procedure time and radiation exposure between these two approaches, while preserving the safety benefit of RA versus FA.

In our study we found that post procedure complications were statistically insignificant between both groups. However, hematomas were seen in 7.5 % of trans-femoral approaches compared

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to none in the radial group; this was in agreement with ***Bhat et al.***[4]who reported hematomas were seen in 14.5% of transfemorals compared to none in the radial group. Additionally, thrombophlebitis was more common in the transfemoral group (17.5%) compared to only (8%) in transradial group with ($p < 0.05$).

Our results also were in agreement with ***Vefali et al.*** [9]who foundin their study that only minor complications were seen during transradial approach, most commonly being pain and ecchymosis. 5.4% of the patients developed hematoma at the access site in the transfemoral group and the results of our study were comparable with the above study.

Access site bleeding was absent in both groups in our study. This was not in agreement with ***Bhat et al.*** [4]who reported that bleeding complications were seen in a significantly higher number of patients in the TFA compared to TRA. Also the TFA group had a higher number of more severe bleeding episodes.

In our study, the non-access site bleeding was evident in one patient in the transfemoral group &that was statistically insignificant. This was in agreement with ***Romagnoli et al.***[6]who found in his study thatthe non-coronary artery bypass grafting–related major bleeding was reduced with the radial approach (7.8% vs. 12.2%, p = 0.026), driven by a 62% reduction in access-site bleeding (2.6% vs. 6.8%, p =0.002). And in agreement with ***Bernat et al.***[7]who found in his study that bleeding or access-site complications at 30 days was declined by 80% in radial access when compared with femoral access (1.4% vs.7.2%, p = 0.0001).

Interestingly, overall bleeding was not reduced in these studies, largely because non–access site bleeding was not different for the RA and FA groups, and accounted for at least 50% of overall major bleeding[1].

These data were also in agreement with ***Généreux et al.*** [10]who reported a 55% reduction in the rate of non CABG-related major bleeding at 30 days, due principally to a significant reduction in the occurrence of access site-related large haematomas (≥5 cm). Overt access site-related bleeding and retroperitoneal haematomas also occurred only with the TF approach. Indeed, there were no access site-related bleeds among the 200 patients with STEMI undergoing primary PCI with TR access in this study. The magnitude of the reduction in non CABG-related major bleeding with TR compared to TF access was more evident in patients treated with heparin and *GP IIb/IIIa inhibitors* than with *bivalirudin.* Furthermore, the lowest absolute rates of events were observed in patients treated with bivalirudin and TR access.

In our study, mortality was absent in transradial group compared to transfemoral group. Despite the fact that it was statistically insignificant and may not be referred to bleeding, but it was in agreement with ***Romagnoli et al.*** [6]who reported in his study a significant reduction in mortality with the radial approach as opposed to the femoral approach that was in contrast with ***Bernat et al.*** [7]who found similar mortality rates in RA vs FA (2.3% vs. 3.6%, respectively; p = 0.31) after exclusion of patients with thrombolysis or cardiogenic shock as we had done in our study.

Also, the mortality was decreased with RA versus FA in meta-analysis carried out by ***Karrowni et al.*** [12]. However ***Mahmud and Patel*** [13]cautioned against over interpretation of these observations because of methodologic differences in the studies, and urged for an adequately powered clinical trial to provide a definitive answer to the issue of a reduction in mortality with RA for PPCI for STEMI. Nonetheless, in the absence of a definitive answer to the question of a reduction in mortality with RA, the existing data suggest that at worst RA is equivalent to FA with regard to mortality, and may well be lower[1].

Other major adverse cardiac events (MACE) rather than all cause-death, were absent in both groups in our study, this in contrast with ***Romagnoli et al.***[6]whofound that (MACE) were lower in TR versus TF (7.2% vs. 11.4% respectively, p =0.029) owing mainly to differences in cardiac death (5.2% vs. 9.2%, p = 0.020).Also ***Bernat et al.*** [7] found no difference in (MACE) in TR versus TF (3.5% vs. 4.2% respectively, p =0.7).

We have to consider that the results of our study were obtained after exclusion of patients cardiogenic shock, this was not consistent with ***Iga et al.*** [14]who reported that in patients with AMI complicated with cardiogenic shock TRI had a significantly lower rate of major bleeding and vascular complications within 30 days and 1 year than TFI. No significant differences were observed between the two groups in the MACCE rate within 30 days and 1 year, and the all-cause death rate within 30 days and 1 year. In addition, TRI was not inferior to TFI in terms of door-to-balloon time and PCI procedural success.

Fujii et al. [15]reported in his study to compare between outcomes in AMI patients complicated with cardiogenic shock who underwent PPCI, that cardiopulmonary arrest was commonly observed in both the TR and TF groups (42.1% and 51.2%, respectively). However, The TR group showed a trend

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toward a shorter door to first device activation time compared to the TF group and lower access site complications. But the 30-day mortality rate was 28.9% in TR and 25.6% in TF group.

In our study we found that the hospital stay was less in TR group compared to TF group (2.1±0.38 days versus 4.0±1.0 days respectively, p = 0.001) and it was statistically significant. This was in agreement with ***Bhat et al.*** [(4)]who found that the hospital stay was less in transradial approach group compared to transfemoral group (3.6 ± 1.3 days versus 4.0±1.1 days, p = 0.009) .Also our results were consistent with the study by ***Vefali et al.*** [(9)]**.**

Overall hospital stay is less with transradial approach compared to transfemoral approach which is more needed in the developing countries like our country where there is a scarcity of the hospital beds and the recent increasing burden of coronary artery disease.

In our study we found that the AKI occurred in 2 patients in transfemoral group, despite that the dye volume was similar in both groups. This was in agreement with ***Steinvil et al.*** [(16)]who found that TR-PCI was significantly associated with a reduced rate of AKI. Heart failure, baseline creatinine clearance, bleeding events, and transfusion use were correlated with AKI. The decline in AKI rates was in contrast to baseline clinical characteristics and angiographic and procedural complexity, as patients referred for TF-PCI in this study were older, had significantly higher rates of co-morbidities, presented more often with unstable conditions, and had lower initial creatinine clearance. These patients also had longer in-hospital stay, more vascular and bleeding complications, and higher rates of type C lesion treated.

In our study we found that the ejection fraction (EF) after 1 month was better in the transradial group versus the transradial group. While, peak quantitate troponin and peak CK-MB were higher in the transfemoral versus the transfemoral group. These values may not be referred to difference in the access route, but referred to the small study population size.

CONCLUSIONS:

PPCI for STEMI can be performed via RA with DTBs clinically equivalent to those performed from FA after adequate experience and training. Mortality is the same or possibly lower with RA versus FA for PPCI for STEMI. The shorter in hospital stay reported in RA more than in FA patients may be of influence in morbidity and mortality reduction due to decreased incidence of venous thromboembolic/pulmonary embolism due to early ambulation, decrease in nosocomial infections as a result of early discharge, decreased renal failure due to decreased periprocedural renal embolism, or unknown reasons.

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