The Egyptian Heart Journal 70 (2018) 1-7



# Contents lists available at ScienceDirect

# The Egyptian Heart Journal

journal homepage: www.elsevier.com/locate/ehj



# Transradial artery approach in STEMI patients reperfused early and late by either primary PCI or pharmaco-invasive approach $^{\bigstar, \bigstar \bigstar}$



CrossMark

El-Zahraa M. Sultan<sup>a,\*</sup>, Hoda M. Rabea<sup>b</sup>, Khaled R. abdelmeguid<sup>c</sup>, Hesham B. Mahmoud<sup>d</sup>

<sup>a</sup> Clinical Pharmacist, Cardiovascular Department, Beni-Suef Hospital University, Egypt

<sup>b</sup> Clinical Pharmacy Department, Faculty of Pharmacy, Beni-Suef University, Beni-Suef, Egypt

<sup>c</sup>Lecturer of Cardiology, Beni-Suef Hospital University, Beni-Suef, Egypt

<sup>d</sup> Prof. of Cardiology, Beni-Suef Hospital University, Beni-Suef, Egypt

#### ARTICLE INFO

Article history: Received 28 November 2016 Accepted 21 April 2017 Available online 12 June 2017

Keywords: ST-myocardial infarction Primary PCI Pharmaco-invasive Transradial approach Streptokinase

# ABSTRACT

The purpose of the study was to investigate the safety and efficacy of transradial artery approach (TRA) in STEMI patients who reperfused early ( $\leq$ 3 h from symptoms onset) or late (>3 h from symptoms onset) by either PPCI or pharmaco-invasive strategy (PI), thrombolysis followed by CA. Therefore, a total 143 STEMI patients (who were presented within 12 h from symptoms onset or 12-24 h with an evidence of ongoing ischemia or suffered from an acute STEMI were randomized for either PI or PPCI. Eighty-two patients were assigned to PI arm while the rest assigned were to PPCI arm. Patients who were taken to a non-PCI capable hospital received streptokinase and were then transferred to our Hospital for CA. TRA was used in the catheterization laboratory for all patients. Each arm was divided according to reperfusion time into early and late subgroups. A primary endpoint was death, shock, congestive heart failure, or reinfarction up to 30 days. There was a non-significant difference regarding LVEF in both arms. Myocardium wall preservation was significant in the early PI arm (P = 0.023). TIMI flow had no discrepancy between both arms (P = 0.569). Mean procedural and fluoroscopic time were  $35.1 \pm 6.1$  and  $6.3 \pm 0.9$  min. There were no reported entry site complications. There was no difference in primary endpoint complications (P = 0.326) considering the different times of patients' reperfusion (early; P = 0.696 vs. late; P = 0.424). In conclusion, it is safe and effective to use TRA in STEMI patients who reperfused by either early or late PPCI or PI. We recommend PI for STEMI patients with delay presentation if PPCI is not available.

© 2017 Egyptian Society of Cardiology. Production and hosting by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

# 1. Introduction

The key strategy in the acute STEMI management is timedependent, the reperfusion,<sup>1</sup>. Since most of STEMI patients do not present to a PCI-capable hospital, they do not have myocardial reperfusion by the primary PCI within recommended times of guidelines. Such delay results in an increased morbidity and mortality.<sup>2</sup> The majority of patients with STEMI particularly in developing countries, present to non-PCI facilities and reperfused via thrombolytic therapy followed by systematically performing an angiography.<sup>1</sup>

The benefit of fibrinolytic therapy in patients with STEMI is well established: pre-hospital or in-hospital thrombolysis. It is evident that the early routine post-thrombolysis coronary angiography followed by PCI (if required) reduced the incidence of reinfarction and recurrent ischemia.<sup>3</sup> In contemporary practice, it is all about increased antiplatelet activity as early as possible. Accordingly, the bleeding complications are expected with the use of adjuvant pharmacological treatment: antiplatelet and anti-coagulant therapy. Such complications could result in increased mortality and the duration of hospitalization after thrombolysis and PCI procedures. This fact could push us toward the use of transradial approach (TRI) more in the catheter. The aim of this study was to investigate the safety and efficacy of the transradial artery

http://dx.doi.org/10.1016/j.ehj.2017.04.001

Abbreviations: PPCI, Primary percutaneous coronary intervention; TRI, Transradial approach; EF, Ejection fraction; SWMA, segmental wall motion abnormality; VSR, ventricular septal rupture; TFG, TIMI flow grade; ACS, acute coronary syndromes; MR, acute mitral regurgitation; TFI, transfemoral intervention.

 $<sup>\,\,^*</sup>$  This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

 $<sup>\</sup>dot{}^{\star\star}$  We recommend PI for STEMI patients with delay presentation if PPCI is not available.

Peer review under responsibility of Egyptian Society of Cardiology.

<sup>\*</sup> Corresponding author.

*E-mail addresses:* Zahraaesmat.713@gmail.com (E.-Z.M. Sultan), Hoda\_cp@ yahoo.com (H.M. Rabea), Krefaat20@yahoo.com (K.R. abdelmeguid), heshamboshra@ gmail.com (H.B. Mahmoud).

approach in STEMI patients who were reperfused early ( $\leq$ 3 h from the onset of symptoms) or late (>3 h from the onset of symptoms) by either PPCI or PI and also to detect whether the best approach to deal with STEMI patients in Beni-Suef city is to give immediate thrombolytic once the patient is diagnosed or transferred for PPCI with some delay.

# 2. Materials and methods

# 2.1. Study population and area

Patients who present to the ER within 12 h from the onset of symptoms or 12–24 h with an evidence of ongoing ischemia, acute STEMI on electrocardiogram were enrolled during the period from July 2014 to February 2016. The exclusion criteria were (1) patients presented to the hospital at a time more than 24 h from the onset of symptoms or with no evidence of an ongoing ischemia, (2) current or previous diagnosis of congestive heart failure, and (3) a patient with a contraindication to thrombolytic therapy will be excluded from the pharmaco-invasive arm. Beni-Suef is located near to the capital Cairo (Fig. 1). It consists of 7 small centers (Fig. 2) and it has only one governmental PCI capable University hospital to serve all STEMI patients who arrived at the center either within crucial hours of the reperfusion or later.

#### 2.2. Study protocol

All eligible STEMI patients were randomized for either pharmaco-invasive approach or primary PCI according to the patients' arrival time in the ER. Eighty-two patients underwent thrombolysis with streptokinase followed by coronary angiography. The rest were assigned to primary PCI arm. The randomization process was done according to the patients' arrival time to the University center (with two catheterization laboratories, GE and PHELIPS). All patients arrived during working hours (from 8:00 am to 5:00 pm) underwent primary PCI. Patients who arrived after working hours (from 5:30 pm to 7:30 am) received streptokinase followed by coronary angiography. STEMI patients reached a non-PCI capable hospital received streptokinase and were transferred to the hospital for coronary angiography. Coronary angiography and PCI were performed via the transradial artery approach in both arms by an expert in this approach (doing at least



Fig. 1. Location of Beni-Suef city on Egypt map.



Fig. 2. Districts of Beni-Suef city; 7 centers: Beni-Suef, Wasta, Naser, Ehnasya, Beba, Somosta, Al Fashn, respectively.

500 cases per year through radial approach). Based on the reperfusion time, the arms were divided into two subgroups: early reperfusion ( $\leq$ 3 h from the onset of symptoms) or late reperfusion (>3 h from the onset of symptoms). Gender was similar in both groups: early and late reperfusion in PPCI and PI arm. Patients in the pharmaco-invasive arm received streptokinase (1.5 million units over 40-60 min) in a combination with LMWH: enoxaparin (30-mg intravenous bolus followed by SC injection of 1 mg/kg or 0.75 mg/kg for patients  $\geq$ 75 years every 12 h). The dose was omitted in patients ( $\geq$ 75 years). LMWH was also received by PPCI arm. A 300 mg loading dose clopidogrel (not used for patients more than 75 years) followed by 75 mg daily and aspirin was given for both arms as an antiplatelet therapy. Glycoprotein IIb/IIIa antagonists were administrated in some selected cases during the urgent or routine coronary angiography followed by intervention or not, left to the operator's decision. In the case of hemodynamic or electrical instability, worsening ischemia, or progressive or sustained STsegment elevation in the pharmaco-invasive arm, an urgent coronary angiography was performed immediately. Echocardiographic examination was done for all patients. Ejection fraction (EF), LV dimensions and segmental wall motion abnormality (SWMA) were measured. Acute complications of MI such as ventricular septal rupture (VSR), acute mitral regurgitation (MR), aneurysm and LV thrombus were looked for. Final TIMI flow grade result (TFG) was obtained. Bleeding complications were also observed and evaluated. All patients were followed up for 30 days.

# 2.3. Endpoints

The primary endpoint is a composite of death, shock, congestive heart failure, or reinfarction up to 30 days. A secondary endpoint consists of ischemic stroke, intracranial hemorrhage and nonintracranial bleeding.

# 2.4. Statistical analysis

Data were analyzed using the software, Statistical Package for Social Science (SPSS) version 20, and then processed and tabulated. Frequency distribution with its percentage and descriptive statistics with mean and standard deviation were calculated. Chisquare, *t*-test, and correlations were done whenever needed. *P*values of less than 0.05 were considered significant.

# 3. Results

## 3.1. Comparisons of baseline clinical characteristics

Although the mean age was lower in the early group, it did not show a significant difference (P = 0.181). Late reperfused patients were more diabetic than the early reperfused one (P = 0.020 vs. P = 0.242). Electrocardiogram baseline was more or less similar in both groups except that the late group did not have posterior ECG Ischemic changes. Baseline clinical characteristics of the patients are summarized in Table 1.

#### 3.2. Coronary angiography and PCI procedural characteristics

There was a significant difference regarding the use of a suction device between PPCI and PI arms: (27%) vs. (9.4%) (P = 0.005) with an increase in the late PPCI group; n = 10 (25.6%). There was also a tendency to use IV Epitfibatide in PPCI more than PI; n = 12 (19.0%) vs. n = 7 (8.3%); (P = 0.048), especially in the late PPCI group; n = 10 (25.6%). The TIMI grade was similar in both early reperfused patients (P = 0.494) and late (P = 0.660) for both PPCI and PI arms.

Regarding the lesions in the PCI, there was no statistical difference between early and late reperfusion (P = 0.284 vs. P = 0.333) in both PPCI and PI (P = 0.340) (Table 2).

Mean procedural and fluoroscopic times were estimated at  $35.1 \pm 6.1$  min and  $6.3 \pm 0.9$  min simultaneously. Furthermore, there were no entry site complications. Mean amount of contrast was  $90 \pm 21$  s. One or two injections were done for the non-culprit vessel with a diagnostic catheter, then guiding catheter for culprit vessel.

#### Table 1

Baseline clinical characteristics.

#### 3.3. Post-PCI characteristics

Echocardiography showed no difference between both arms. LVEF ( $54.0 \pm 8.5$  vs.  $52.8 \pm 10.6$ ; P = 0.459) and end diastolic volume (ED) ( $5.0 \pm 0.6$  vs.  $4.9 \pm 0.6$ ; P = 0.688) had similar results. Early and late reperfusion also did not show a statistical difference except for end systolic volume (ES) ( $3.5 \pm 0.5$  vs  $3.8 \pm 0.5$ ; P = 0.019) for early, late reperfusion vs. ( $3.7 \pm 0.5$  vs.  $3.9 \pm 0.7$ , P = 0.368). Segmental wall motion abnormality was better in PPCI than PI with more hypokinetic segments and more preserved wall thickness, although that was not statistically significant (P = 0.635).

Regarding complications, there was no difference between PPCI patients and PI. Only two cases had minor bleeding complications in PI group; n = 2 (2.4%) (P = 0.326).

# 4. Discussion

#### 4.1. STEMI management in current practice

The current state of STEMI management becomes more complicated despite all clear guidelines in many countries. Since artery reperfusion is the key to STEMI management,<sup>4</sup> previous literature is developed in and outside catheterization laboratory to get the best results. Despite that primary percutaneous coronary intervention (PPCI) is more effective than thrombolytic therapy alone when delivered by an experienced team soon after symptom onset, in our developing countries, frequent delays to PPCI are standing against the perfect time of myocardial reperfusion. In our city Beni-Suef, the delay of reperfusion is for many reasons: (1) City traffic; as STEMI patients cannot reach PCI capable hospitals at an appropriate time. Also, many patients are getting there by taxi or by their own cars and unfortunately, ambulances are minimally used to transfer STEMI patients to hospitals; (2) the lack of patients' awareness of STEMI symptoms and the importance of getting to the hospital for an early reperfusion. This delay adversely affects outcomes.<sup>5</sup> A recent approach of using fibrinolytic followed by transfer for early PCI (pharmaco-invasive) has been shown to be effective in reperfused STEMI patients presenting to non-PCI hospitals compared with fibrinolysis alone.<sup>6</sup>

Transradial access (TRA) is becoming increasingly used worldwide in PCI after acute coronary syndromes (ACS), especially in STEMI patients who undergo primary PCI.<sup>7</sup> TRA results in STEMI patients showed reductions in major bleeding events with lower short- and long-term mortality rates.<sup>8</sup>

		Total ( <i>n</i> = 143)			≤3 h ( <i>n</i> = 79)			>3 h ( <i>n</i> = 64)		
		PPCI ( <i>n</i> = 61)	PI ( <i>n</i> = 82)	P value	PPCI ( <i>n</i> = 22)	PI ( <i>n</i> = 57)	P value	PPCI ( <i>n</i> = 39)	PI ( <i>n</i> = 25)	P value
Age Mean ± SD		52.9 ± 9.9	55.1 ± 9.8	0.181	50.6 ± 7.7	54.6 ± 9.8	0.092	54.2 ± 10.9	56.4 ± 9.9	0.425
Gender	М	50 (79.4%)	66 (77.6%)	0.483	19(79.2%)	43 (75.4%)	0.479	31 (79.5%)	31 (79.5%)	0.521
	F	13 (20.6%)	19 (22.4%)		5 (20.8%)	14 (24.6%)		8 (20.5%)	5 (17.9%)	
Medical his	story									
Diabetes	-	24 (38.1%)	24 (28.2%)	0.138	5 (20.8%)	18 (31.6%)	0.242	19 (48.7%)	6 (21.4%)	0.020
HTN		30 (47.6%)	30 (35.3%)	0.090	11 (45.8%)	18 (31.6%)	0.166	19 (48.7%)	12 (42.9%)	0.411
Smoking		32 (50.8%)	48 (56.5%)	0.110	11 (45.8%)	33 (57.9%)	0.111	21 (53.8%)	15 (53.6%)	0.554
Addiction		1 (1.6%)	3 (3.5%)	0.430	1 (4.2%)	1 (1.8%)	0.507	0	2 (7.1%)	0.171
HCV		7 (11.1%)	5 (6.0%)	0.204	3 (12.5%)	2 (3.5%)	0.151	4 (10.3%)	3 (11.1%)	0.608
ECG										
Anterior		35 (55.6%)	51 (60.0%)	0.354	11 (45.8%)	32 (56.1%)	0.272	24 (61.5%)	19 (67.9%)	0.394
Inferior		29 (46.0%)	34 (40.0%)	0.286	13 (54.2%)	24 (42.1%)	0.226	16 (41.0%)	10 (35.7%)	0.428
Lateral		4 (6.3%)	2 (2.4%)	0.212	1 (4.2%)	1 (1.8%)	0.507	3 (7.7%)	1 (3.6%)	0.441
Posterior		0	1 (1.2%(	0.574	0	1 (1.8%)	0.704	0 (0%)	0 (0%)	-

PPCI: Percutaneous coronary intervention, PI: pharmaco-invasive, M: Male, F: female, HTN: Hypertension, HCV: Hepatitis C virus, LM: Left main, LAD: Left atrial ascending, D: diagonal, RCA: Right coronary artery, LCX: Left circumflex, OM: Obtuse marginal.

*P* value  $\leq$  0.05 is significant.

# Table 2

Characteristics of PCI procedure.

		Total ( <i>n</i> = 143)			≤3 h ( <i>n</i> = 79)			>3 h ( <i>n</i> = 64)		
		PPCI ( <i>n</i> = 61)	PI ( <i>n</i> = 82)	P value	PPCI ( <i>n</i> = 22)	PI ( <i>n</i> = 57)	P value	PPCI ( <i>n</i> = 39)	PI ( <i>n</i> = 25)	P value
Baseline cor	ronary angiog	raphy								
Culprit lesion	n									
LM		2 (3.2%)	1 (1.2%)	0.393	1 (4.2%)	0	0.296	1 (2.6%)	1 (3.7%)	0.655
LAD		31 (49.2%)	41 (48.8%)	0.547	11 (45.8%)	23 (40.4%)	0.415	20 (51.3%)	18 (66.7%)	0.161
D		2 (3.2%)	0	0.180	1 (4.2%)	0	0.296	1 (2.6%)	0	0.582
RCA		19 (30.2%)	30 (35.7%)	0.299	9 (37.5%)	24 (42.1%)	0.448	10 (25.6%)	6 (22.2%)	0.493
LCX		9 (14.3%)	6 (7.1%)	0.122	2 (8.3%)	3 (5.3%)	0.467	7 (17.9%)	3 (10.7%)	0.323
OM		2 (3.2%)	0	0.180	1 (4.2%)	0	0.296	1 (2.6%)	0	0.582
Non-culprit	lesion									
LAD		11 (17.5%)	14 (17.3%)	0.574	4 (16.7%)	9 (17.0%)	0.625	7 (17.9%)	5 (17.9%)	0.626
RCA		9 (14.3%)	9 (10.6%)	0.333	1 (4.2%)	8 (14.0%)	0.186	8 (20.5%)	1(3.6%)	0.045
LCX		9 (14.3%)	7 (8.2%)	0.183	2 (8.3%)	6 (10.5%)	0.560	7 (17.9%)	1 (3.6%)	0.075
OM		6 (9.5%)	7 (8.2%)	0.503	4 (16.7%)	4 (7.0%)	0.176	2 (5.1%)	3 (10.7%)	0.344
Culprit done										
LAD		31 (50.8%)	47 (57.3%)	0.340	11 (45.8%)	29 (52.7%)	0.284	20 (54.1%)	18 (66.7%)	0.333
D		1 (1.6%)	1 (1.2%)		1 (4.2%)	0 (.0%)		0 (.0%)	1 (3.7%)	
LCX		9 (14.8%)	5 (6.1%)		2 (8.3%)	3 (5.5%)		7 (18.9%)	2 (7.4%)	
OM		1 (1.6%)	0 (.0%)		3 (5.5%)	0 (.0%)		0	0	
RCA		19 (31.1%)	29 (35.4%)		9 (37.5%)	23 (41.8%)		10 (27.0%)	6 (22.2%)	
Procedure										
Suction		17 (27.0%)	8 (9.4%)	0.005	5 (20.8%)	6 (10.5%)	0.187	12 (30.8%)	2 (7.1%)	0.018
IV Epit.		12 (19.0%)	7 (8.3%)	0.048	2 (8.3%)	5 (8.9%)	0.650	10 (25.6%)	2 (7.1%)	0.049
TIMI	G 2	4 (6.3%)	6 (7.1%)	0.569	1 (4.2%)	3 (5.3%)	0.660	3 (7.7%)	3 (10.7%)	0.494
	G 3	59 (93.7%)	79 (92.9%)		23 (95.8%)	54 (94.7%)		36 (92.3%)	25 (89.3%)	
		== (=51770)	. = (3210,0)		== (=510,0)	2 2 (3 117,0)		(,,,,,)	(5015/0)	

PPCI: Percutaneous coronary intervention, PI: pharmaco-invasive, LAD: Left atrial ascending, D: diagonal, LCX: Left circumflex, OM: Obtuse marginal, RCA: Right coronary artery, Epit: Epitifibatide, TIMI: Thrombolysis in Myocardial Infarction, G: grade. a scoring system ranging from 0 to 3, as follows: 0, the absence of antegrade flow beyond a coronary occlusion; 1, faint antegrade coronary flow beyond the occlusion with incomplete filling of the distal coronary bed; 2, delayed or sluggish antegrade flow with complete filling of the distal coronary bed; and 3, normal flow that completely fills the distal coronary bed.

\* *P* value is  $\leq$  0.05 is significant.

4

Table 3	
Clinical outcomes after PO	CL.

	Total ( <i>n</i> = 143)			≤3 h ( <i>n</i> = 79)			>3 h ( <i>n</i> = 64)		
	PPCI ( <i>n</i> = 61)	PI ( <i>n</i> = 82)	P value	PPCI ( <i>n</i> = 22)	PI $(n = 57)$	P value	PPCI ( <i>n</i> = 39)	PI $(n = 25)$	P value
Complication Primary Secondary	0.0% 0.0%	0.0% 2 (2.4%)	- 0.326	0.0% 0 (.0%)	0.0% 1 (1.8%)	- 0.696	0.0% 0 (.0%)	0.0% 1 (3.6%)	- 0.424
Echo data EF ED ES	$54.0 \pm 8.5$ $5.0 \pm 0.6$ $3.6 \pm 0.5$	52.8 ± 10.6 4.9 ± 0.6 3.8 ± 0.6	0.459 0.688 0.076	57.4 ± 7.8 5.0 ± 0.5 3.5 ± 0.5	53. ± 10.2 4.9 ± 0.5 3.8 ± 0.5	0.071 0.572 0.019	52.0 ± 8.3 5.0 ± 0.6 3.7 ± 0.5	52.2 ± 11.5 5.0 ± 0.7 3.9 ± 0.7	0.930 0.748 0.368
<i>Motion</i> Akinesia Hypo-Kinesia Normal	19 (30.2%) 24 (38.1%) 20 (31.7%)	29(34.1%) 35(41.2%) 21(24.7%)	0.635	2 (8.3%) 10(41.7%) 12(50.0%)	21(36.8%) 21(36.8%) 15(26.3%)	0.020 <sup>°</sup>	17(43.6%) 14(35.9%) 8 (20.5%)	8 (28.6%) 14 (50.0%) 6 (21.4%)	0.413
Wall Preserved Thinned-out	51 (81.0%) 12 (19.0%)	69(81.2%) 16(18.8%)	0.568	24(100%) 0(.0%)	47(82.5%) 10(17.5%)	0.023	27(69.2%) 12(30.8%)	22 (78.6%) 6 (21.4%)	0.286

PPCI: Percutaneous coronary intervention, PI: pharmaco-invasive, EF: ejection fraction, ED; end diastolic, ES; end systolic.

\* *P*-value  $\leq$  0.05; this is a statistical difference.

# 4.2. TRA efficacy in STEMI patients reperfused early ( $\leq$ 3 h) or late (>3 h) by PPCI or PI

In our study, there was no statistical significant difference regarding the LVEF result in both PPCI and PI arms (P = 0.459). Early and late reperfusion in both strategies did not show a difference; (P = 0.071) and (P = 0.930). When comparing myocardium wall preservation in PPCI and PI arms it showed no statistical difference; (P = 0.568). Early PI reperfusion group ( $\leq 3$  h) had more preserved walls; (P = 0.023) comparing to early PPCI. This difference was not noticeable in late reperfusion group (>3 h). While late PPCI and late PI had nearly the same results; 27(69.2%) vs. 22 (78.6%), (P = 0.286), forty-seven 47 patients (82.5%) in early PI group had preserved myocardium wall versus 24 (100%) patients in early PPCI, Table 3. This result shows a clear benefit of TRA in early reperfusion, especially by PI strategy.

Final TIMI flow in both arms (PPCI and PI) did not show a significant difference (P = 0.569). Early and late reperfusion subgroups showed the same incidence of open vessels. 95.8% of patients in early PPCI reach TIMI G3 versus 94.7% in early PI, while only one patient (4.2%) in early PPCI and three patients (5.3%) in early PI had final TIMI G2 (P = 0.660), Table 2. These results are going along with those published in Stream trial (P = 0.41)<sup>2</sup> STREAM showed that 91% of PI patients had reach TIMI G3 flow and only 5.3% reached G2 flow. In PPCI arm, 92.3% of patients had G3 and 3.7% had G2. On the other hand, our results could be promising considering that late PI reperfused group had same final TIMI grade as for late PPCI. TIMI G3 had reached in 92%3 of late PPCI and only 7.7% of patients had G2. In late PI, 89.3% of patients had TIMI G3 and also 10.7% patients had G2 as a late PPCI group. STREAM was including patients who were presented within only 3 h from symptom onset, in contrast to our study which includes patient presented in within 3 h (early) or more (late).

A significant difference was clear between early (P = 0.187) and late reperfusion (P = 0.018) subgroups regarding the use of the suction device in catheterization laboratory. The suction device was used in 10.5% (n = 6) in early reperfusion by PI comparing to early PPCI group; 20.8% (n = 5). The real difference had shown in late PPCI versus late PI group; 30.8% (n = 12) vs. 7.1% (n = 2). This result could be explained by the fact that the thrombus which is propagated in the lumen, mainly consists of fibrin and red blood cells with a minimal platelet component.<sup>9</sup> Late reperfusion after 3 h of symptom onset means more time for thrombus complexity formation. Plasminogen-activating agents convert plasminogen to

plasmin that can degrade fibrin. Fibrin-selective agents such as Tenecteplase and alteplase are known to be efficient in lysing thrombi with less inducement of coagulation factor depletion or steal plasminogen in contrast to non-fibrin-selective agents.<sup>10</sup> Many famous trials, WEST, CAPITAL-AMI, GRACIA-1, CARESS-IN-AMI TRANSFER-AMISTREAM and STEPP AMI had used fibrinselective agents.<sup>1</sup> Our data show a low incidence of suction device used with late PI group comparing to late PPCI and even early PI. This significant result was achieved by using Streptokinase (nonfibrin specific agent). Intravenous Eptifibatide was used in case of high thrombus burden situations only.<sup>3</sup> In late reperfusion by PI approach, only 2 (7.1%) patients need IV Eptifibatide in catheterization laboratory comparing to 10 (25.6%) patients in late PPCI (P = 0.049). Early reperfusion did not show a significant difference (P = 0.650). This result is expected in early reperfusion and it goes along with our previous results of using the suction device.

# 4.3. TRA safety in STEMI patients reperfused early ( $\leq$ 3 h) or late (>3 h) by PPCI or PI

# 4.3.1. Bleeding and other complications

While TRA is becoming widely used in different countries, still many interventionists have concerns regarding TRA in STEMI patients such as bleeding complications. According to our study, Reperfusion efficacy using PPCI or PI strategies was proved by reaching a satisfying results regarding LVEF, wall thinning and final accepted TIMI flow when using TRA as an approach of accesses.

Minimal bleeding complications were noticed. There were no documented primary endpoint complications during the 30-day follow-up in both arms. Secondary outcome was reached in both arms. There was no difference between both PPCI and PI strategies (P = 0.326). Consider different times of patients' reperfusion in both arms (early reperfusion vs. late reperfusion); (P = 0.696) vs. (P = 0.424). The PPCI arm had no complications while PI patients had only two complications: Ischemic stroke and minor bleeding (non-Intra cranial bleeding). No difference was found between both arms in STREAM regarding the increase in Ischemic strokes (P = 0.40). In PI arm 21.8% of patients got ischemic strokes and 20.2% in PPCI arm. Failed reperfusion by SK was reported in 5 patients without any further complications after rescue PCI or within 30 day follow-up. It is noticeable in our study that late PI reperfusion group had the same incidence of complications comparing to early reperfusion by PI. The same findings were described in the TRANSFER-AMI<sup>11,12</sup> and FAST-MI registry.<sup>13</sup> Both trials raised the issue of using PI approach in reperfused STEMI patients. In TRANSFER-AMI, Major artery access in patients was femoral.<sup>14</sup> TRANSFER-AMI included STEMI patients presented within 12 h of symptom onset to non-PCI centers and received the standard dose of tenecteplase. The study concluded that it is better to transfer STEMI patients for PCI within six hours of receiving fibrinolytic at a non-PCI hospital than adopting the wait-and-see strategy. FAST-MI registry assessed 5-year mortality in STEMI patients who reperfused by either PI, PPCI or did not reperfuse at all. A study was done in our department was comparing radial accesses with femoral access. The result reveal that only one case of major bleeding and two of minor bleeding were detected in the femoral arm, while radial arm did not show any bleeding complications.<sup>15</sup>

#### 4.3.2. Failure of canulation of radial artery

No failure of cannulation the radial artery was documented. Also no crossover from radial to femoral was reported. No Bifurcation lesions were treated by TRA. A launcher guiding catheter (Medotronic production) was used. Its inner lumen is 0.073 mm which allows two balloons or one stent and one balloon. The mean procedural time was estimated in our study by  $28.83 \pm 7.54$  min. This value was comparable to transfemoral procedural time result in our center; mean  $26.15 \pm 9.15$ .<sup>15</sup>

Access site crossover from radial to femoral was estimated by 3.7% in STEMI-RADIAL trial.<sup>16</sup> A year after, other study was published by Roberts et al. and estimated a crossover rate by 0.2% when using one sublingual nitroglycerin tablet and ultrasound imaging of the radial and ulnar arteries in all patients.<sup>17</sup> A higher rate of crossover to another vascular access and lower risk of access-site complications also was reported in a meta-analysis which compared radial versus femoral access in patients with previous Coronary Artery Bypass Grafting.<sup>18</sup> Improvement in crossover results could be explained by increasing the learning curve and operators' experience in different centers.<sup>19</sup> Other factors may include the patient's gender according to Huang et al. A higher crossover rate in the TR intervention (P = 0.05) was estimated by authors. They conclude that TR intervention may improve the safety and efficacy of outcomes in both genders.<sup>20</sup> The SAFE-PCI for Women also concludes same results.<sup>21</sup> In a Meta-analysis and Subgroup analysis when comparing radial to femoral access for CA and PCI, elderly patients (>75 years) had more crossover rate from radial approach fewer vascular complications.<sup>22</sup>

The fluoroscopic time mean was  $6.43 \pm 3.42$  min which also was close to our center transfemoral result; mean  $5.9 \pm 1.2$ .<sup>15</sup> These outcomes are somehow contrasting other published Trials<sup>23,24</sup> and matching others.<sup>25</sup> Also mean amount of contrast used in TRA in some published data was comparable to our.<sup>25</sup>

Our results comparing to other published data show the capability of our center to deal effectively with such an emergency situation via TRA, safely and without significant time consuming. Fewer vascular access site bleeding complications, immediate post-procedural ambulation, and no postural limitation are important advantages of TR intervention. Early reperfusion using PI approach is highly recommended by our center if the alternative is late PPCI. Late PI seems to be effective and safe as PPCI in the case of patient presentation to non-PCI capable hospital.

The limitation of this study is the small sample size. We tried to overcome this problem by sticking to our randomization method.

# 5. Conclusions

It is safe and effective to use transradial approach for STEMI patients who were reperfused by either PPCI or PI approach (early or late). Early pharmaco-invasive is good alternative modality in STEMI patients if PPCI is unavailable.

# **Conflict of interest**

We declare that we have no conflict of interest.

#### Acknowledgment

We thank Dr. Arafa A. for providing the statistical analysis, and El dakly K. for providing language help and writing assistance.

## References

- Dalal J et al.. 2013 consensus statement for early reperfusion and pharmacoinvasive approach in patients presenting with chest pain diagnosed as STEMI (ST elevation myocardial infarction) in an Indian setting, JAPI. 2014;62:473.
- Armstrong PW et al.. Fibrinolysis or primary PCI in ST-segment elevation myocardial infarction. New Engl J Med. 2013;368(15):1379–1387.
- **3.** Steg PG et al.. ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation. *Euro Heart J.* 2012;ehs215.
- Wang Y-B et al., Thrombolysis followed by early percutaneous coronary intervention via transradial artery approach in patients with ST-segment elevation infarction. Acta Cardiol Sin. 2014;30(4):284.
- Herrmann HC et al., Benefit of facilitated percutaneous coronary intervention in high-risk ST-segment elevation myocardial infarction patients presenting to nonpercutaneous coronary intervention hospitals. JACC: Cardiovasc Intervent. 2009;2(10):917–924.
- Larson DM et al.. Safety and efficacy of a pharmaco-invasive reperfusion strategy in rural ST-elevation myocardial infarction patients with expected delays due to long-distance transfers. *Euro Heart J.* 2012;33(10):1232–1240.
- Amin AP et al.. Costs associated with transradial primary pci among elderly patients with STEMI in the medicare fee-for-service beneficiaries. J Am Coll Cardiol. 2016;67(13):16.
- Khan R, Ly HQ. Transradial percutaneous coronary interventions in acute coronary syndrome. *Am J Cardiol*. 2014;114(1):160–168.
   Van de Werf F, Topol E, Sobel B. The impact of fibrinolytic therapy for ST-
- Van de Werf F, Topol E, Sobel B. The impact of fibrinolytic therapy for STsegment-elevation acute myocardial infarction. J Thromb Haemost. 2009;7 (1):14–20.
- **10.** Cantor WJ et al.. Routine early angioplasty after fibrinolysis for acute myocardial infarction. *New Engl J Med.* 2009;360(26):2705–2718.
- 11. Olympios CD. Routine early coronary angioplasty after thrombolysis. *Hosp Chron*. 2010;5(3):127–132.
- **12.** Bagai A et al.. Clinical outcomes and cost implications of routine early PCI after fibrinolysis: one-year follow-up of the Trial of Routine Angioplasty and Stenting after Fibrinolysis to Enhance Reperfusion in Acute Myocardial Infarction (TRANSFER-AMI) study. *Am Heart J.* 2013;165(4):630–637. e2.
- Cambou J-P et al.. The F rench registry of A cute ST elevation or non-STelevation M yocardial I nfarction (FAST-MI): study design and baseline characteristics. Archives des maladies du coeur et des vaisseaux. 2007;100(6– 7):524–534.
- 14. Madan M et al.. Relationship between time to invasive assessment and clinical outcomes of patients undergoing an early invasive strategy after fibrinolysis for ST-segment elevation myocardial infarction: a patient-level analysis of the randomized early routine invasive clinical trials. *JACC: Cardiovasc Intervent*, 2015;8(1):166–174.
- 15. Mabrok M, Amein O, Boshra H. Transradial versus Transfemoral artery approach for Coronary angiography and percuteaneous intervention in Obease patients regarding vascular complications*Cardiology and cardiovascular disease*. Beni-Suef University; 2017.
- Bernat I et al.. ST-segment elevation myocardial infarction treated by radial or femoral approach in a multicenter randomized clinical trial: the STEMI-RADIAL trial. J Am Coll Cardiol. 2014;63(10):964–972.
- 17. Roberts JS, Baumann F. Radial artery to femoral artery crossover rate of 0.2% in 557 consecutive patients undergoing cardiac catheterization/percutaneous coronary intervention. *J Am Coll Cardiol*. 2015;65(10):A1833.
- Rigattieri S et al.. Meta-analysis of radial versus femoral artery approach for coronary procedures in patients with previous coronary artery bypass grafting. *Am J Cardiol.* 2016;117(8):1248–1255.
- **19.** Applegate RJ. Radial access for primary percutaneous coronary intervention for ST-segment elevation myocardial infarction: time for a paradigm shift? *J Am Coll Cardiol.* 2014;63(10):973–975.
- Huang F-Y et al.. Gender disparity in the safety and efficacy of radial and femoral access for coronary intervention: a systematic review and metaanalysis. *Angiology*. 2016;67(9):810–819.
- **21.** Rao SV et al.. A registry-based randomized trial comparing radial and femoral approaches in women undergoing percutaneous coronary intervention: the SAFE-PCI for Women (Study of Access Site for Enhancement of PCI for Women) trial. *JACC: Cardiovasc Intervent.* 2014;7(8):857–867.
- 22. Lynch C et al.. TCT-364 radial vs femoral access for coronary angiography and intervention in the elderly (>75)-a meta-analysis and subgroup analysis (all studies vs octagenarian studies, N. America studies vs rest of the world studies). J Am Coll Cardiol. 2016;68(18):B149.

- 23. Sinha SK et al.. Coronary angiography safety between transradial and transfemoral access. *Cardiol Res Pract.* 2016;2016.
  24. De Raya M et al.. Trans-radial vs. trans-femoral radiation exposure and
- 24. De Raya M et al.. Trans-radial vs. trans-femoral radiation exposure and screening times for diagnostic coronary angiography at Sydney Southwest Private Hospital. *Heart, Lung Circ.* 2015;24:S311.
- 25. Singh S et al.. The fluoroscopy time, door to balloon time, contrast volume use and prevalence of vascular access site failure with transradial versus transfemoral approach in ST segment elevation myocardial infarction: a systematic review & meta-analysis. *Cardiovasc Revascular Med.* 2015;16 (8):491–497.