ORIGINAL ARTICLE

Trans-radial Primary Percutaneous Coronary Intervention in ST-Elevation Myocardial Infarction

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ABSTRACT

Objective: To study the effect of trans-radial approach (TRA) on achievement of a door-to-balloon time (DBT) of ≤ 90 minutes in primary PCI percutaneous coronary intervention (PPCI) for ST-elevation myocardial infarction (STEMI).

Study Design: Case series.

Place and Duration of Study: Armed Forces Institute of Cardiology - National Institute of Heart Diseases (AFIC -NIHD), Rawalpindi, from October 2011 to August 2012.

Methodology: Systems goal for door-to-balloon time (DBT - time elapsed between first medical contact and restoration of flow in the infarct related artery [IRA]) was set at < 90 minutes. Procedural success was defined as restoration of TIMI 3 flow in the IRA with less than 30% residual stenosis and discharge from hospital. Non-infarct related arteries were not treated. Bleeding episodes were defined by TIMI definitions.

Results: For vascular access for PPCI in a total of 207 patients, TRA was 91.3% (n = 189), transfemoral approach (TFA) 6.3% (n = 13) and brachial 2.4% (n = 5). Males represented 90.3% of cases and 7% were females. Mean age was 55 ± 10.86 years. Procedural success rate was 97.1%. Mean DBT was 54.1 minutes. DBT was less ≤ 60 and 90 minutes in 75% and 94.2% of patients respectively. DBT ≤ 89.50 minutes was achieved in 90% of patients. The difference in DBT between the different access groups was not markedly different between the three groups. There were 6 (2.9%) in-hospital deaths and no major bleeds.

Conclusion: TRA for PPCI poses no hindrance to achieving a DBT of < 90 minutes in PPCI for STEMI. Furthermore, the in-hospital mortality rates are acceptable and within rational limits.

Key Words: *Primary percutaneous coronary intervention. STEMI. Door-to-balloon time. Angioplasty. Transradial approach.*

INTRODUCTION

Primary PCI percutaneous coronary intervention (PPCI) is a life saving intervention for ST-elevation MI (STEMI) and it has been shown to be effective for appropriate patients.[1,2] Although some studies may suggest that the door-to-balloon time (DBT) should be less than 60 minutes. The current standard of care for performing PPCI is to achieve a DBT of < 90 minutes to achieve mortality benefit.[3,4] The trans-radial access (TRA) for performing PCI has been shown to be beneficial for reducing bleeding complications. However, the TRA for PCI has a learning curve which must be covered and needs training.[5,6] This training required to overcome this learning curve includes timely, good quality radial access, overcoming local vascular access problems such as spasm, preventing extravasations and perforations in the radial artery, managing cross overs to TFA promptly and finally the most important; handling of the guide catheter and then performing the actual PCI procedure. The actual procedure times tend to reduce over a period of time as the PPCI by TRA program takes root.[5,7] The femoral route obviates these problems and is relatively easy to learn with relatively simpler handling of the guide catheters and hence quicker PCI. The downside of the femoral access route has always been bleeding complications which in the long-run have been shown to adversely affect outcomes.[8,9] New closure devices to secure hemostasis have been shown to reduce bleeding complications,[10,11] however, they are expensive.

A large number of studies have been done to investigate whether TRA for PPCI is better than TFA in terms of reducing bleeding complications while maintaining DBTs within the systems goals.

The aim of this study was to determine effect of the trans-radial approach on achievement of a systems goal of achieving a DBT of ≤ 90 minutes in PPCI for STEMI.

METHODOLOGY

The study population consisted of all patients undergoing PPCI enrolled in the registry at AFIC - NIHD, Rawalpindi, from October 2011 to August 2012. Registry records were accessed to collect demographic data, risk factor profiles, cardiovascular risk factors and procedural details. DBTs were recorded from the database and bleeding episodes were looked up from patient's source notes.

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All the PPCI procedures were performed by consultant interventional cardiologists. For this study, systems goal for door-to-balloon time in AFIC - NIHD was set at 90 minutes. Procedural success was defined as restoration of TIMI 3 flow in the IRA with less than 30% residual stenosis and discharge from hospital. Non-infarct related arteries were imaged at the end of the procedure using a separate diagnostic catheter; however, they were not treated as per institutional protocol. All patients received Group IIb-IIIa inhibitors (either Abciximab or Tirofiban). For access site hemostasis no vascular closure devices were used, and manual compression / compression dressings were used for securing hemostasis after removal of vascular sheaths once the activated clotting time had fallen to less than 150 seconds. Heparin reversal was not done after any procedures. Bleeding episodes were defined by TIMI definitions.[1]

We also sought to compare door-to-balloon time between the TRA, TFA and brachial groups. Because of the difference in sample size of the three groups non-parametric statistical tests were applied to compare medians (median test) and compare mean ranks (Kruskal-Wallis test).

RESULTS

A total of 207 patients underwent PPCI from October 2011 to August 2012. Of the 207 patients, 91.3% (n=189) of PPCI were performed from radial artery, 6.3% (n=13) from femoral artery, and 2.4% (n=5) from the brachial artery. Males represented 90.3% of cases and 9.7% were females. Mean age was 55 ± 10.86 years ranging from 27 to 90 years. Coronary artery disease risk factor distribution is given in Table I. Territorial distribution and IRA frequencies are given in Tables II and III respectively. In terms of Killip class, 72.7% were in class-I, 22.5% in class-II, 2% in class-III and 2.9% in class-IV. Three patients were admitted with cardiac arrest. There were 6 (2.9%) in-hospital deaths. Procedural success rate was 97.1%. TFA was used due to operator preference and not due to TRA failure. Brachial route was used due to failure of TRA. Temporary pacing lead was required in 9 patients for which the femoral vein access was used. Thrombus aspiration was done in 45 patients (21.7%). Mean DBT was 54.1 minutes (median 50 minutes; minimum 15 minutes; maximum of 270 minutes). DBT was less ≤ 60 minutes in 75% of patients. In term of percentiles for the DBT, the 90th percentile value was 89.50 minutes. The DBT of ≤ 90 minutes was achieved in 94.2% of patients. The difference in DBT between the different access groups was insignificant between the three groups (Kruskal Wallis test; p=0.3; median test p=0.2). There were 6 (2.9%) in-hospital deaths. There were no major bleeding event.

Table I: Coronary artery disease risk factor distribution.

Risk factor	Frequency	Percentage
Smoking	76	36.7%
Diabetes mellitus	45	21%
HTN	56	27%
Family history of IHD	30	14.5%

Table II: Territorial distribution of the STEMI.

MI location/ distribution	Frequency	Percent
Extensive anterior	20	9.7
Antero-septal	94	45.4
Inferior	70	33.8
Inferior+Rv	9	4.3
Infero-lateral	10	4.8
High lateral	4	1.9
Total	207	100.0

Table III: Infarct related artery.

Infarct related artery	Frequency	Percent
LAD	109	52.7
LCX	19	9.2
RCA	76	36.7
LAD+Diagonal	2	1.0
Major diagonal	1	0.5
Total	207	100.0

DISCUSSION

The standard of care for STEMI is to perform PPCI in suitable candidates in centers where a DBT less than 90 minutes is achievable in patients suitable for the PPCI.[4] To achieve this systems goal of DBT < 90 minutes, all factors from triage to the first balloon inflation which restores flow in the IRA are important, as increase in DBT is associated with increased in-hospital mortality.[12,13] This includes decision time after first medical contact, transfer time to the cardiac catheterization laboratory from the emergency department, time to attain vascular access, seating the guide and crossing the lesion with the angioplasty wire. All this is usually being done at a very high speed for a patient who already has or does occasionally develop complications such as cardiogenic shock, cardiac arrest or pulmonary edema. The time to vascular access is one factor which is in the control of the first operator on the case. Although TFA appears to be quicker, there are concerns about bleeding complications especially with the increasing use of glycoprotein IIb-IIIa inhibitors in PPCI.

One of the major concerns with TRA during PPCI is that of delay in obtaining access and having to cross over to the TFA. A large scale study of 2209 patients showed that TRA for PPCI has low access site crossover, high procedural success rates and excellent procedural performance. It is thus a safe option for access in PPCI.[7] Investigators found TRA to be a safe and effective option in short statured South Asian females without any increased risk of complications.[14] One meta-analysis

and systematic review showed that the rate of access site crossover was tended to be higher with TRA (p=0.06).[15]

To ensure timely restoration of flow in the IRA and coronary angiography of non-IRA through TRA use of a single guiding catheter has shown to be feasible and highly successful and allows timely restoration of blood flow.[16] In another retrospective study of 362 patients, TRA with a single Ikari Left (IL) guide catheter for STEMI was compared to conventional TFA in 185 patients. There were no failed radial cannulations. There were only 2 (non-access site related) procedural failures that required conversion to TFA. Compared to TFA, TRA with IL tended to have a shorter median door to perfusion time (p=0.07), shorter median procedure duration (p=0.06), however, these differences were statistically insignificant. Although MACE were similar between the two groups, the median fluoroscopy duration was longer in the TRA group.

There is data to suggest that PPCI from TRA is associated with decreased 2-year mortality rates and a reduction is the need for vascular surgery and/or blood transfusion compared with TFA.[17] In a major meta-analysis and systematic review involving 8,534 patients in trials from 2001-2011.[15] TRA was associated with a significant reductions in major adverse cardiac events ($p < 0.001$), mortality ($p < 0.001$), and major bleeding ($p < 0.001$) compared to TFA. There were no differences in fluoroscopic time, door-to-balloon time, and procedure time between the two access routes (p=0.09, p=0.38, p=0.82, respectively). The meta-analysis by Singh *et al*. of seven randomized trials involving 1306 patients showed that compared with patients undergoing TFA, risk of major adverse cardiovascular events (p=0.45) and major bleeding (p=0.14) was similar in patients undergoing TRA.[18] The procedural success was similar with both approaches (p=0.59). However, incidence of access site complications was significantly lower in the TRA group ($p < 0.001$).

Getting hardware down the guide catheter can pose a problem through TRA due to the tortuosity of the subclavian vessels or the aortic arch morphology as well as the axial orientation of the guiding catheter with the coronary ostium. Thrombus aspiration from TRA has also been compared with TFA. In a single center study of 303 patients equally randomized to either route, thrombus aspiration was deemed feasible and efficacious from the TRA.[19] Similar results were found in another small scale study.[20] TRA for PPCI also reduces the hospital stay for elderly patients. One hundred and sixteen patients > 80 years of age were studied in a single center. Compared to TFA, TRA was associated in a reduction of CCU stay to less than 3 days (p=0.02).[21]

In the registry data the major access route was TRA. However, even with this access route in the first year of a formal PPCI program a 90th percentile of 89.50 minutes for DBT (90% patients had a DBT ≤ 90 minutes) was achieved. Data from another center in-Pakistan have shown a DBT of 98.4 minutes with an in-hospital mortality of 4.9%.[22] In a tertiary care center in a developing country achievement of DBT < 90 minutes is possible by setting-up protocols and ensuring adequate manpower and protocol adherence. In the developing world financial constraints of the patients and the hospital also delay the decision-making process for PPCI.

In-hospital mortality from another center in Pakistan was reported at 8.3%.[23] The in-hospital mortality in this study was 2.9%, of these only one patient was in Killip class I, while the other five were brought in cardiac arrest or cardiogenic shock, thus already having a high predicted pre-procedure mortality. Three had extensive anterior MI, while three had inferior MI with RVMI.

Although prescription of Group IIb-IIIa inhibitors was universal and femoral vein access was needed in 6.7% (femoral) and 2.4% (brachial) of patients there was still no increase in the bleeding complications. There was no difference between the different access site groups in term of DBT. In addition, there were no major bleeding events. The reason for there being no difference in bleeding is probably because of the small number of femoral procedures in the registry, and any such difference may be highlighted with increasing number of procedures. There were no failures of the thrombus aspiration devices from TRA.

The major limitation of the study is that this is based on registry data and not randomized data. There is a clear and disparate male preponderance in this registry data; however, this is almost the same as data from another center in Pakistan.[22] Although the appropriate statistical tests to correct for the non-normal distribution in the smaller sized groups have been used however, these results may vary if the data was randomized and equal numbers from each access site were available.

CONCLUSION

This registry data shows that TRA for PPCI poses no hindrance to achieving a DBT of < 90 minutes in PPCI for STEMI. Furthermore, the in-hospital mortality rates are acceptable and within rational limits.

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