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COMPARISON OF OUTCOMES IN PRIMARY PCI ACCORDING TO ARTERIAL ACCESS SITE: A FOUR-YEAR SINGLE CENTRE OBSERVATIONAL STUDY

Omar Rana [1], Daniel Vawdrey [2], Lain Simpson [3], Alison Calver [4], Simon Corbett [5], James Wilkinson [6], Huon Gray [7], Nick Curzen [8]

[1]Omar Hospital and Cardiac Center, Lahore- Pakistan

[2-8]Wessex Cardiac Unit University Hospital, Southampton-UK

Address for Correspondence:

Omar Rana

Omar Hospital and Cardiac Center, Lahore- Pakistan

E-mail: omarrana78@gmail.com

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OR, DV collected the data. OR analysed the data and wrote the draft manuscript. This manuscript was reviewed by IS, AC, SC, JW, HG, NC and modified accordingly. All authors have read and approved the final version of the manuscript which is being submitted. All authors contributed significantly to the submitted manuscript.

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ABSTRACT

Objective: To compare outcomes following femoral artery (FA) and radial artery (RA) access for consecutive patients undergoing primary percutaneous coronary intervention (PPCI) over a four-year observational period

Methodology : This cross sectional study was conducted at University Hospital Southampton . All PPCI cases performed at our center over a four-year period (1st April 2008 to 31st March 2012) were rewired. Patients more than 18 years of age were included . Procedural decisions including access site, device selection, use of adjunctive pharmacotherapy and type of stent were at the operator discretion. Cardiologists delivering the PPCI service, three used RA access , while the other three used FA access and outcomes between these two groups was recorded. All data were analysed using SPSS statistical software, (Version 20.0, IBM Corporation, Armonk, NY, USA).

Results : Our study included 961 patients (64±12 years, 76% males). There was no significant difference in door-to-balloon times, radiation dose or in-hospital length of stay between the RA and FA groups. In-hospital mortality rates were higher in FA group vs. RA group (6.8% vs. 2.0%, p=0.009). However, following the exclusion of cardiogenic shock patients, the in-hospital mortality rates were no different, 2.4% vs. 4.3%, (p=0.10). There was a higher rate of combined vascular complications in the FA group (1.4% vs. 0%, p=0.05). RA access was associated with a higher screening time (minutes) 9 (3 to 15) vs. 7.5 (0.5 to 14.5) (p<0.0001) and access site failure 2.8% vs. 0.1% (p<0.0001).

Conclusion: Our data demonstrates that in patients without cardiogenic shock undergoing PPCI, there is no significant difference in outcomes for FA versus RA access.

Key Words : Primary PCI , Radial Access , Femoral Access , Cardiologists

INTRODUCTION

Primary percutaneous coronary intervention (PPCI) is the gold standard treatment for ST-elevation myocardial infarction (STEMI).[1] Concomitant development of antiplatelet and antithrombotic regimens has resulted in improved patient survival.[2-5] However, the use of potent antithrombotic drugs inevitably increases the risk of bleeding, including at the arterial access site, which is an independent risk factor for mortality.[6-8] Furthermore, antithrombotic regimens associated with reduced bleeding rates have been shown to improve survival rates.[9]

Conventionally, femoral artery (FA) approach has been the preferred route of access for coronary interventional procedures. However, use of the radial artery (RA) approach has increased rapidly over the last decade. One of the dominant drivers for this was the clear advantage of RA in terms of access site bleeding. Initial observational studies confirmed this reduction in bleeding, and in some there was an associated lower mortality in patients undergoing PPCI by a radial approach.[10-15] Furthermore, recent randomised trials have indeed suggested significantly lower mortality in RA patients compared to FA in the context of PPCI.[16,17]

However, for many PCI operators, their training has been exclusively femoral, and re-training in the RA approach is therefore challenging, particularly in the context of services which are increasingly dominated by non-elective rather than elective PCI, and when speed of intervention is so important for PPCI cases.[18] In addition, for established, highly experienced interventional cardiologists using FA access, the complication rates using this route may be much lower than for a more general group of interventionalists included in studies. Furthermore, adopting certain manoeuvres, such as screening the femoral head prior to an arterial puncture, and use of arterial closure devices, can reduce the risk of access site bleeding and vascular complication rate making FA access PCI safer.[19] These factors are difficult to incorporate into a randomised trial, but may have important influence on patient care in a real world setting. In our centre, out of the six highly experienced consultant interventional cardiologists who deliver a 24/7, 365 day PPCI service, three use RA access site by default while three use the FA access site. In this observational study, we assessed whether there were procedural and outcome differences between the RA/FA access routes in our real world single centre experience, and compared this to data from randomised study.

METHODOLOGY

This cross sectional study was conducted at University Hospital Southampton. University Hospital Southampton NHS Foundation Trust is a tertiary care hospital which provides health care facilities to a population of 500,000. It provides a 24-hour PPCI service which is centrally controlled and activated by a team of six specialist acute coronary syndrome nurses. The ambulance services are able to transmit an electrocardiogram (ECG) of a patient with cardiac-sounding chest pain to a central workstation MobiMed™ (Ortivus, Danderyd, Sweden). Following this, the PPCI team is activated if any of the following criteria are met: suggestive symptoms of myocardial ischaemia with ST-elevation of at least 1 mm in at least two contiguous ECG leads, or presumed or confirmed new left bundle branch block, or ST-segment depression of 1 mm in at least two leads in V1 through to V3 with a positive terminal T wave. Cardiogenic shock patients were included and were defined according to the criteria used in the "Should we emergently revascularise Occluded Coronaries for cardiogenic shocK" (SHOCK) trial.[20] All patients undergoing PCI received heparin, aspirin and clopidogrel in accordance with current guidelines.[21] Procedural decisions including access site, device selection, use of adjunctive pharmacotherapy and type of stent were at the operator discretion. Of the six interventional cardiologists at our institute delivering the PPCI service, three use RA access as their default approach, while the other three use FA access exclusively for PPCI. This study assesses the outcome differences between these two groups.

All patients included in this single centre retrospective study were above the age of 18 years. We reviewed all PPCI cases performed at our centre over a four-year period (1st April 2008 to 31st March 2012), with case identification and data collection achieved and cross referenced via: British Cardiovascular Intervention Society (BCIS) database, Myocardial Ischemia National Audit Project (MINAP) database, Current Radiology Information Services (CRIS) database and individual patients' case notes. The end points in our study were: door-to-balloon times, fluoroscopy time (minutes), radiation dose (μGy/cm^2), vascular site haematoma of $>$ 4 cm or causing delay in discharge from hospital, incidence of false arterial aneurysm (FAA), combined vascular complications (significant haematoma + FAA), in-hospital length of stay and in-hospital mortality rate, access site failure rate and a drop in haemoglobin of $\geqslant$ 3.0 g/dL necessitating a blood transfusion.

All data was analysed using SPSS statistical software, (Version 20.0, IBM Corporation, Armonk, NY, USA). Categorical variables are presented as number (percentage) whereas continuous variables are presented as mean $\pm$ standard deviation or median (interquartile range) for normally and non-normally distributed data respectively. Between the RA and FA groups, continuous data were compared using the Student t and Mann-Whitney U tests for normally and non-normally distributed data respectively. Furthermore, categorical variables were compared between the two groups using a Chi-Square test. Finally, within the RA and FA groups, age-related and annual trends were compared using the analysis of variance (ANOVA) test.

RESULTS

Our study included 961 consecutive patients undergoing PPCI at our centre over the four-year period. The baseline demographics of the patients are shown in Table 1. Of note, 11 patients were in hospital either undergoing treatment for a concurrent medical condition, or had been admitted with chest pain but only subsequently developed ST-elevation on their ECGs. The door-to-balloon time was not applicable to these patients. About fifty nine patients presented with cardiogenic shock. Two hundred and fifty six patients comprised the RA access group whereas 705 patients formed the FA access group. This difference reflects recruitment of two of the six members of the consultant group providing PPCI during the study period. The default access site strategy for each operator was well defined, so that no operator usesd both access routes as a default. Thus, in year one, only 9% PPCI cases were performed using the RA access (Figure 1). This increased to 22% in year two and plateaued in year three at 19%. However, in year four this rate increased significantly to 44% ($p<0.0001$ vs. RA access rates of previous years). Cross over of access from RA to FA access occurred in 7 cases (0.3%) and was due to either radial cannulation failure; failure to achieve access to the coronaries from the radial access point; radial spasm; cardiogenic shock or a clear indication for intra-aortic balloon pump use. In contrast, cross over from FA to RA occurred in one case (0.1%) as a result of severe peripheral vascular disease.The groups were well-matched for clinical characteristics (Table 1). However, there were more patients with intra-aortic balloon pump (IABP) usage in the FA access group in comparison to the RA access group (7% vs. 1%, $p<0.0001$). These results suggest an operator preference to utilise FA access in patients presenting with cardiogenic shock requiring up-front use of an IABP. Importantly, 11 of these patients (1.1%) had had previous coronary artery bypass grafting (CABG) and all underwent PPCI using FA access.

Thirteen percent of the patients undergoing PPCI during the four-year period were aged 80 years or older. In addition, the proportion of patients aged 60 years or younger and between 61-79 years was 52% and 35% respectively. We further examined the interaction between age and arterial access. Our data demonstrated that the rate of RA access in patients 60 years or younger was 28% where as the rate of RA access in patients 61-79 years and 80 years or above was 26% and 21% respectively. There was no significant difference in the rate of RA access between the three age groups (Figure 2).

The duration of screening (minutes) was significantly longer ($p<0.0001$) in the RA access group, 9 (3 to 15) vs. the FA access group 7.5 (1 to 15). There was no difference in the door-to-balloon times, total radiation dose, length of in-hospital stay (days), FAA or significant haematomas (Table 2). There was no statistical difference in the number of patients requiring a blood transfusion in either group (1.2% vs. 2.8%, $p=0.14$). However, the combined vascular complication rate was increased in the FA access group in comparison to the RA group and this was at a level of

Table 1: Demographic variables PPCI Groups (n=961).

	Radial Group	Femoral Group	P value
Number	256	705	
Age (years)	64±12	65±12	0.20
Males (%)	75	76	0.89
Diabetes (%)	11	10	0.83
History of ischemic heart disease (%)	11	16	0.06
History of smoking (%)	69	67	0.42
Family history (%)	40	31	0.008
Dyslipidaemia (%)	44	37	0.05
Hypertension (%)	40	45	0.42
History of stroke (%)	4	4	0.98
Peripheral vascular disease (%)	5	5	0.99
Cardiogenic shock (%)	3	7	<0.0001

Figure 1: Yearly Trends for Radial and Femoral Access in All Patients Undergoing PPCI Over a Four-Year Period. The Percentage of Radial Cases Performed are Shown in Each Bar (n=961).

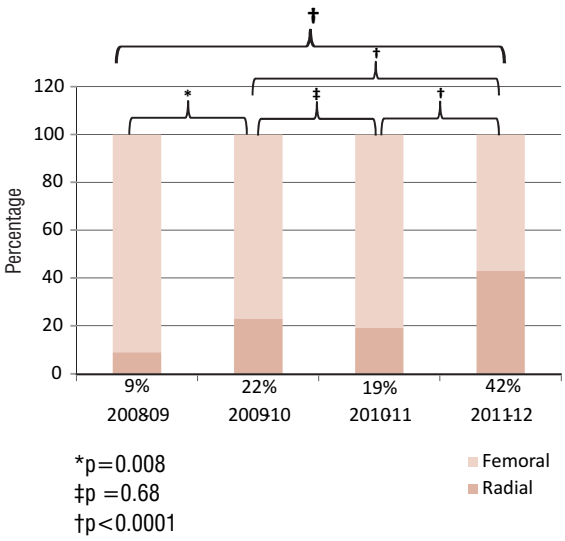
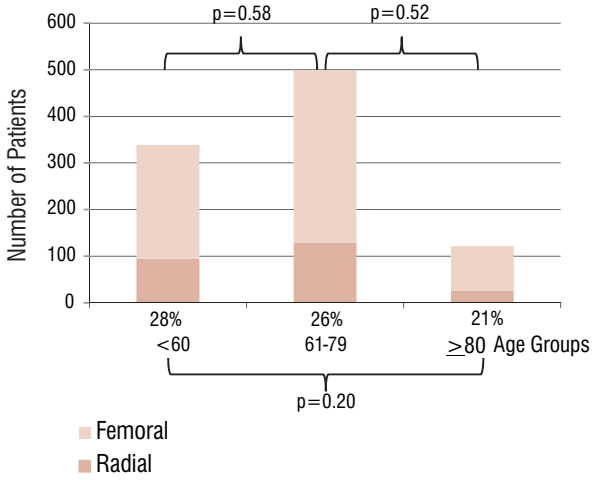


Figure 2: The Comparison of Radial And Femoral Access In Patients Undergoing PPCI Over the Four-Year Period According to The Age of The Patients (n=961).



borderline significance (1.4% vs. 0%, p=0.05). Of note, the rate of access site failure was significantly higher in the RA group as compared to the FA group (p<0.0001).

The total in-hospital mortality rate for the entire cohort was 5.5% (including patients presenting in cardiogenic shock). With the inclusion of patients in cardiogenic shock, the in-hospital mortality rate in the RA access group was 2% vs. 6.8% in the FA access group (p=0.009), but as indicated above those with cardiogenic shock (and its associated higher mortality) were disproportionately in the FA rather than RA access group. In contrast, the in-hospital mortality rate was 3.8% for the entire cohort when cardiogenic shock cases were excluded, the in-hospital mortality rates in the FA and RA groups being 4.3% and 2.4% respectively (p=0.10). Again, the screening time (minutes) was longer in the RA group, 9 (3 to 15) vs. the FA group, 7.4 (1 to 13, p<0.0001). There was no difference between the two groups in the door-to-balloon times, total radiation dose, in-hospital length of stay, prevalence of FAA or significant haematomas (Table 3). However, the prevalence of combined vascular complications was greater in the FA group vs. the RA group (1.5% vs. 0%, p=0.05). Patients with combined vascular complications had a significantly longer in-hospital length of stay, 5 (0 to 10), in comparison to patients without combined vascular complications, 3 (1 to 5), (p=0.025). The rate of access site failure was higher in the RA group (2.8%) vs. the FA group (0.2%, p<0.0001). Finally, there was no difference in the number of patients requiring a blood transfusion in either group (1.2% vs. 1.9%, p=0.46).

The in-hospital mortality rate in patients with cardiogenic shock was 32% and 3.8% in those without (p<0.0001). In addition, the door-to-balloon time was longer in patients with cardiogenic shock 118 (36 to 200) vs. 73 (18 to 128), (p<0.0001), their screening time [12.4 (2.6 to 27.4) vs. 8 (1 to 5), (p<0.0001)] and radiation dose [8883 (2195 to 15571) vs. 5834 (569 to 11119), (p=0.001)] were greater,

Table 2: Outcomes in Radial and Femoral PPCI groups Including Patients Presenting with Cardiogenic Shock (n=961).

	Radial Group (256)	Femoral Group (705)	P value
Door-to-balloon time (minutes)	77 (20 to 134)	74 (19 to 129)	0.48
Screening time (minutes)	9 (3 to 15)	7.5 (0.5 to 14.5)	<0.0001
Radiation dose	6338 (1082 to 11594)	5819 (289 to 11345)	0.46
In-hospital stay (days)	3 (1 to 5)	3 (1 to 5)	0.07
In-hospital mortality (%)	2	6.8	0.009
30-day mortality (%)	3.9	7.5	0.047
False arterial aneurysms (%)	0	0.7	0.18
Significant haematoma (%)	0	0.8	0.18
Total vascular complications (%)	0	1.4	0.05
Access site failure (%)	2.8	0.1	<0.0001
Blood transfusion (%)	1.2	2.8	0.14

and their hospital length of stay longer 6 (1 to 13) vs. 3 (1 to 5), (p<0.0001) when compared to those without cardiogenic shock.

DISCUSSION

Our data reveal several important findings. Firstly, in a group of consecutive patients undergoing PPCI, following the exclusion of patients in cardiogenic shock, there was no significant difference in hospital or 30-day mortality rates according to RA or FA access. Secondly, in the cohort of patients including cardiogenic shock, the in-hospital and 30-day mortality rates were higher in the FA group in comparison to the RA group. However, this reflects the fact that the majority of patients presenting in cardiogenic shock underwent PPCI from the FA, which reflects current practice.[16] Finally, there was no difference in either the need for blood transfusion or the incidence of FFA between the RA or FA groups, although the risk of a combined vascular complication was slightly increased in the FA group, though at a level of borderline statistical significance.

The radial versus femoral randomized investigation in ST-elevation acute coronary syndrome (RIFLE-STEACS) study compared RA to FA in 1001 patients undergoing PPCI.[16] The investigators noted a reduction in the 30-day cardiac mortality rate by 4 % (a difference of 20 patients) in the RA group in comparison to the FA group. In addition, on average

Table 3: Outcomes in Radial and Femoral PPCI Groups Excluding Patients Presenting with Cardiogenic Shock (n=961).

	Radial Group (248)	Femoral Group (654)	p value
Door-to-balloon time (minutes)	77 (21 to 133)	72 (20 to 124)	0.20
Screening time (minutes)	9 (3 to 15)	7.4 (1.4 to 13.4)	<0.0001
Radiation dose	6373 (1250 to 11496)	5541 (266 to 10816)	0.16
In-hospital stay (days)	3 (2 to 4)	3 (1 to 5)	0.13
In-hospital mortality (%)	2.4	4.3	0.10
30-day mortality (%)	3.2	5.5	0.20
False femoral aneurysms (%)	0	0.8	0.17
Significant haematoma (%)	0	0.9	0.13
Total vascular complications (%)	0	1.5	0.05
Access site failure (%)	2.8	0.2	<0.0001
Blood transfusion (%)	1.2	1.9	0.43

the FA group patients stayed one day longer in hospital and the risk of non-CABG related bleeding was larger in the FA group which was mainly driven by increased minor bleeding rates. Importantly, as the trial was not-double blinded, patients presenting with cardiogenic shock were 3-fold more likely to undergo PPCI through the FA. Furthermore, 19 more patients with Killip class presentation II-IV underwent the procedure from the FA. Finally, the rate of access site failure was 6% in the RA group which is comparable to our findings.

The trial of trans-radial versus trans-femoral percutaneous coronary intervention access site approach in patients with unstable angina or myocardial infarction managed with an invasive strategy (RIVAL) study was notably different from the RIFLE-STEACS trial.[17] Patients were ineligible to take part if they presented in cardiogenic shock and importantly, 1 in 8 patients had undergone rescue PCI following failed thrombolysis. Of note, the rate of bivalirudin and GPIIb/IIIa administration was low in comparison to contemporary trials. It was noted that there was no advantage of RA access versus FA access in patients with non-ST elevation myocardial infarction. However, in patients presenting with STEMI, there was a 61% reduction in absolute in-hospital mortality rates. In addition, there was no difference in the rate of minor bleeding, major bleeding or stroke and therefore, the mechanism behind a reduction in total mortality was not clear. Furthermore, there were several confounders in the final analysis that could have influenced the results, for example the patients who died within 30 days (44 patients, 2.3%) were older, had a higher prevalence of diabetes mellitus, stent thrombosis, major bleeding and requirement for blood transfusion. In addition, the cross-over rates to a FA access from RA were also greater in the patients who died within 30 days, although not a single patient developed a vascular site complication in that group.

A recently published large UK-based registry has compared outcomes in patients undergoing PPCI via RA and FA.[22] Using sophisticated statistical analyses, this registry demonstrated that RA access in patients undergoing PPCI was independently associated with a reduction in 30-day mortality, major bleeding and access site complication rates. However, it is important to note that the RA and FA groups were not well-matched and had important differences in the clinical characteristics. For example, the FA group included older patients, more female patients, as well as a greater number of patients with previous myocardial infarction and/or CABG. In addition, more patients in the FA group were in cardiogenic shock, received haemodynamic support with IABP and paradoxically, fewer patients received GPIIb/IIIa inhibitors or had thrombectomy device usage. Subsequently, increasing age, the lack of GP IIb/IIIA use, IABP usage, severe LV impairment and cardiogenic shock emerged as independent risk factors for increased mortality at 30 days. Propensity-matched analysis was performed with exclusion of the confounding factors and an absolute risk reduction of 1% was observed in the 30-day mortality rate in the RA group in comparison to the FA group.

More recently, the minimizing adverse haemorrhagic events by transradial access site and systemic implementation of angiox (MATRIX) trial examined the effect of vascular access

site in patients presenting with an acute coronary syndrome.[23] More than 8000 patients were either randomized to RA or FA. There was no significant difference in the primary outcome of major adverse cardiovascular events (MACE, defined as all-cause mortality, myocardial infarction or stroke). In contrast, the rate of net adverse cardiovascular events (NACE, defined as major bleeding unrelated to coronary artery bypass graft surgery or MACE) was statistically higher in the FA group mainly in consequence of greater bleeding rates (1.6% vs. 2.3%; p=0.013). However, closer examination of the data revealed that in centres where FA was performed more commonly (up to 85% of all cases) there was no significant difference in either MACE or NACE rates. In other words, there was no net benefit for patients who underwent interventional procedures using the FA in comparison to RA in centres where FA access was used routinely. On the contrary, the rate of adverse events was higher in centres where FA was less routinely used (<20% of cases). Thus the outcomes were dependent on the centre's experience of using either the RA or FA.[24]

In the current study, we have been able to assess the differences in procedural and clinical outcomes according to the access route in circumstances in which half of the operators use FA and the other 3 use RA as a default. Whilst this approach has several clear limitations, which are discussed in detail below, it provides an insight into the comparison between these access routes in a real world cohort that cannot be reproduced in a randomised trial. The findings indicate that the clinical outcome of FA access in PPCI, if undertaken by highly experienced operators who use FA as a default, are not inferior to RA, once cardiogenic shock cases have been excluded. Specifically, the mortality is not higher under these real world circumstances. However, slightly more patients in the FA group did experience some form of vascular complication and in a few of these this resulted in a prolonged hospital stay.

LIMITATIONS

Our study has inherent limitations as it is a single-centre retrospective study. The number of patients in each group is relatively small in comparison to recently published multi-centre registries. The number of patients in our study with a history of CABG was very small and therefore, no meaningful conclusion can be drawn about this cohort of patients from our results. However, our data are unique as an equal number of consultants prefer RA access over FA access in PPCI and vice-versa. In addition, we examined the trends over a four-year period to lend our results more validity. Furthermore, we have an excellent local follow-up programme of all our PPCI patients with a dedicated team of ACS nurses who ensure any complications are noted and followed up.

CONCLUSION

In conclusion, in a consecutive series of non-randomised PPCI patients, our data showed no overall difference in clinical outcomes for FA versus RA access in a centre in which access and procedures are performed by consultant operators highly experienced in their preferred arterial access routes. Whilst there is obvious and intuitive attraction for the radial approach for patients with STEMI, the evidence for its superiority is currently suggestive rather than conclusive, as reviewed by National Institute for Health & Care Excellence (NICE).[25] It is possible that the excellent published results of the radial approach from randomised trials of PPCI may, at least in part, be influenced by the expertise of operators already highly experienced in this approach. In contrast, the concept that very experienced femoral approach operators should be urged to retrain in the radial approach may be flawed, particularly given the importance of volumes of experience and outcome with the radial approach.[26] In our opinion, further trial data are required.

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