Primary percutaneous coronary intervention for acute ST-segment elevation myocardial infarction - changing patterns of vascular access, radial versus femoral artery.

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Objective: To examine the safety and efficacy of emergency transradial primary percutaneous coronary intervention for ST-elevation myocardial infarction.

Design: Single-centre observational study with prospective data collection.

Setting: A Regional Cardiac Centre, United Kingdom.

Patients: 1051 consecutive patients admitted with ST-elevation myocardial infarction, without cardiogenic shock, between November 2004 and October 2008.

Interventions: Percutaneous coronary interventions by radial and femoral access

Main outcome measures: The primary outcome measures were procedural success, major vascular complication and failed initial access strategy. Secondary outcomes were in-hospital mortality and major adverse cardiac and cerebrovascular events, needle-to-balloon times, contrast volume used, radiation dose absorbed and time to discharge. Multiple regression analysis was used to adjust for potential differences between the groups.

Results: 571 patients underwent radial access and 480 femoral. A variable preference for radial access was observed amongst the lead operators (between 21% and 90%). Procedural success was similar between the radial and femoral groups, but major vascular complications were more frequent at the site of femoral access (0% radial versus 1.9% femoral, $p=0.001$). Failure of the initial access strategy was more frequent in the radial group (7.7% versus 0.6%, $p<0.001$). Adjustment for other procedural and clinical predictors did not alter these findings. Needle-to-balloon time, as a measure of procedural efficiency, was equal for radial and femoral groups.

Conclusions: In the setting of acute ST-elevation myocardial infarction without cardiogenic shock, transradial primary angioplasty is safe, with comparable outcomes to a femoral approach and a lower risk of vascular complications.

INTRODUCTION

Early treatment of ST elevation myocardial infarction (STEMI) with primary percutaneous coronary intervention (PPCI) has been shown to improve outcomes compared to treatment with thrombolysis.[1] The concomitant need for full anticoagulation and multiple anti-platelet therapies including aspirin, clopidogrel, and especially glycoprotein IIb-IIIa inhibitors contributes to the risk of haemorrhagic complications.[2, 3] Bleeding at the site of vascular access is an important source of morbidity and mortality following the procedure.[4]

In both elective and urgent PCI, use of the radial artery compared to the femoral artery as the vascular access route has been shown to have comparable procedural success whilst reducing the incidence of access-related complications and the length of hospital stay post procedure.[5, 6] Other advantages of the transradial approach include facilitating early mobilisation following intervention. A limited number of studies have previously assessed the feasibility of performing PPCI via the transradial route.[7-16] We present observational data on the safety and efficacy of transradial PPCI from a single, high volume UK regional centre.

METHODS

Study Population

The study population consisted of 1051 consecutive patients with STEMI admitted to our unit and treated with PPCI between November 2004 and November 2008. Patients were treated within 12 hours of symptom onset or, occasionally, beyond this if there was ongoing ischaemic pain. Patients who had recently received thrombolysis referred for rescue PCI or for PCI in the setting of re-infarction were not included in this study. Patients with pre-procedural cardiogenic shock (as defined by the British Cardiovascular Intervention Society: blood pressure <100 mmHg; pulse >100 beats per minute; and patient cool, clammy or requiring circulatory support with inotropes) were also excluded, as most required an intra-aortic balloon pump (IABP) via the femoral artery. Patients were admitted either directly to the Cardiology Unit or via the institution's Accident and Emergency department.

Interventional procedures

Coronary angiography was performed via the transfemoral or transradial route, using either 6F or 5F catheters and PCI was undertaken using either 7F or 6F guide catheters from the femoral route and 6F or 5F from the radial route. During the period of study one operator favoured the radial approach throughout as a routine for PPCI cases, whereas the others initially favoured the femoral approach but adopted the radial approach with increasing frequency. Aspirin was given to all patients (unless there was a previous documented hypersensitivity reaction) and bolus intra-arterial heparin was given using a weight-adjusted protocol (to a maximum of 70 units per kilogram). Clopidogrel was administered routinely with a loading dose usually immediately after the procedure, but a few patients received it prior to entering the catheter laboratory. Infarct-related artery flow was determined pre- and post-procedure using the TIMI score, and a score based on that proposed by Duke University was used to assess angiographic severity of coronary artery disease.[17, 18] Use of an IABP (all inserted via the femoral artery) and glycoprotein IIb-IIIa inhibitors were at the discretion of the attending interventionist. When an intra-aortic balloon pump was used, this was in patients with signs of incipient cardiogenic shock

(such as systemic hypotension or poor peripheral perfusion), pulmonary oedema or abnormal antegrade coronary flow (slow reflow) following intervention. As a consequence, IABPs were inserted before, during or after the procedure. Elective stenting was the preferred treatment strategy throughout the study period.

The baseline demographic, procedural and outcome data of all subjects were collected prospectively as part of our quality assurance programme in line with a national prospective audit programme. Outcome data were included and other data verified after discharge by a team of trained validators.

Study outcomes

The primary outcomes of the study were procedural success, major vascular complications and failure of the initial access strategy. Procedural success was defined as restoration of TIMI 3 flow in the infarct-related artery at the procedure end with reduction in the target lesion diameter stenosis to less than 30% of the reference vessel diameter (by visual angiographic assessment). Major vascular complication was defined as access site haemorrhage/haematoma requiring transfusion or delaying hospital discharge or proven false aneurysm formation. Secondary outcomes included in-hospital death or major adverse cardiac or cerebrovascular events (MACCE, defined as death, stroke, emergency CABG, re-infarction or re-intervention to the culprit lesion during the index admission), minor vascular complications (haematoma/haemorrhage not requiring transfusion or delaying discharge), needle-to-balloon time (i.e. from first application of local anaesthetic to first balloon dilatation or first device usage), volume of contrast used, patient radiation dose absorbed and length of hospital stay.

Statistical analysis

Baseline demographic data and outcome measures were compared depending on the initial access strategy, and on an intention-to-treat basis. Initial statistical analyses were performed using χ^2 test and Fisher's exact test (dependant on expected cell counts) for categorical variables and one-way ANOVA for continuous variables, and a subsequent Bonferroni correction was performed, where appropriate. As there were significant differences in operator preference for initial access strategy, with a consequent high likelihood of selection bias (as well as differences in operator technique), the primary outcome data were analysed further using regression modelling. This permitted the identification of independent predictors of the various outcome data, and allowed adjustments to be made. Stepwise logistic regression was used to identify independent predictors of the primary outcome data (procedural success, major vascular complications and failure of the initial access strategy). The lead operator performing the intervention, timing of the procedure (within the first two years versus the last two years), clinical and angiographic variables were included as potential covariates in the model. Variables were entered into the model if the initial univariate analysis had a statistical association at the $p<0.05$ level and subsequently removed if $p>0.10$. Associations between the outcomes and the initial access strategy were then analysed further after adjustment for the other independent predictors. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated. All analysis was performed using SPSS version 12.0 (Chicago, IL).

RESULTS

Baseline characteristics

Baseline clinical characteristics are shown in Table 1. The mean age of the study population (n=1051) was 63.2 ± 12.7 years and 71% were male. Significant differences were observed between the groups in age, gender, body mass index and history of previous PCI (see Table 1).

Table 1. Baseline clinical characteristics.

	Radial approach, n=571	Femoral approach, n=480	p value
Mean age, years (SD)	62.0 (12.5)	64.7 (12.8)	<0.001*
Male, n (%)	428 (75)	319 (66)	0.002*
Current smoker, n (%)	268 (47)	214 (45)	0.430
Hypertension, n (%)	255 (45)	222 (46)	0.563
Diabetes mellitus, n (%)	43 (7.5)	53 (11.0)	0.047
Hypercholesterolaemia, n (%)	433 (76)	357 (74)	0.975
Family history, n (%)	250 (44)	195 (41)	0.684
Body mass index (kg/m^2)	27.1 (24.4-30.2)	26.0 (23.4-29.1)	<0.001*
Previous MI, n (%)	72 (13)	84 (18)	0.026
Previous PCI, n (%)	36 (6.3)	58 (12.0)	0.001*
Previous CABG, n (%)	8 (1.4)	17 (3.5)	0.023
Peripheral vascular disease, n (%)	29 (5.1)	26 (5.4)	0.799
Cerebrovascular disease, n (%)	29 (5.1)	44 (9.2)	0.009
LVF pre-procedure, n (%)	39 (6.8)	29 (6.0)	0.606
Creatinine (µmol/l)	96 (85-107)	97 (86-110)	0.271

MI, myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; LVF, left ventricular failure. Data presented as mean (SD) unless otherwise indicated. * remains significant at p<0.05 level after Bonferroni correction for multiple comparisons

Procedural and angiographic characteristics

Angiographic and procedural characteristics are shown in Table 2. Operator 2 strongly favoured the transradial approach (210/234 cases, 90%) and operator 4 the transfemoral approach (173/220 cases, 79%). The remaining operators performed similar numbers of radial and femoral cases (48-56% transradial). Over the time course of the study, a major shift occurred in access site preference from femoral to radial access (see Figure 1). Graft and left main stem PPCI was relatively uncommon in the cohort (1.1% and 1.7% respectively, Table 2). The vessels to which PCI was attempted were similar between the two groups and there was no difference in the number of vessels or lesions attempted at PCI, or the proportion in which drug-eluting stents (DES) were used. Numerically, more stents were used in the radial group

compared to the femoral group (1.51 vs 1.40) but this was not statistically significant after Bonferroni correction.

Table 2. Angiographic and procedural characteristics.

Outcome	Radial approach, n=571	Femoral approach, n=480	p value
Lead operator preference, n (% of individual operator's activity)			<0.001*
Operator 1	86 (48)	94 (52)	
Operator 2	210 (90)	24 (10)	
Operator 3	110 (56)	86 (44)	
Operator 4	47 (21)	173 (79)	
Operator 5	16 (89)	2 (11)	
Operator 6	102 (50)	101 (50)	
Vessels attempted, n (%)			0.148
Graft	2 (0.4)	10 (2.1)	
Left main stem	11 (1.9)	7 (1.5)	
Proximal LAD	121 (21.2)	94 (19.6)	
Non-proximal LAD	100 (17.5)	93 (19.4)	
LCx	73 (12.8)	58 (12.1)	
RCA	264 (46.2)	218 (45.4)	
Number of vessels attempted	1.05 (0.25)	1.05 (0.24)	0.915
Number of lesions attempted	1.13 (0.40)	1.15 (0.38)	0.320
Drug-eluting stents used, n (%)	221 (39)	189 (39)	0.824
Number of stents used	1.51 (0.99)	1.40 (0.81)	0.042
Duke score pre-procedure	3.9 (2.4)	4.0 (2.4)	0.591
Flow in IRA pre-procedure, n (%)			0.137
TIMI 0	408 (73)	346 (73)	
TIMI 1	26 (5)	38 (8)	
TIMI 2	58 (10)	37 (8)	
TIMI 3	65 (12)	49 (10)	
Flow in IRA post-procedure, n (%)			0.829
TIMI 0	6 (1.1)	9 (1.9)	
TIMI 1	4 (0.7)	4 (0.8)	
TIMI 2	29 (5.2)	27 (5.7)	
TIMI 3	520 (92.7)	433 (91.2)	
Number of lesions success	1.10 (0.40)	1.11 (0.40)	0.742
Intra-aortic balloon pump use, n (%)	18 (3.2)	29 (6.0)	0.024
GP IIb-IIIa inhibitor use, n (%)	527 (92.3)	442 (92.1)	0.899

Thrombus retrieval device used, n (%)	129 (22.6)	74 (15.4)	0.004*

LAD, left anterior descending; LCx, left circumflex; RCA, right coronary artery; IRA, infarct-related artery; GP, glycoprotein. Data presented as mean (standard deviation) unless otherwise indicated. * remains significant at p<0.05 level after Bonferroni correction for multiple comparisons

The angiographic scores recorded at the procedure start and the proportion of patients with TIMI 3 flow in the infarct-related artery (IRA) were similar in each group. At the procedure end, there was no significant difference in the proportion of patients achieving TIMI 3 flow between the groups and the number of lesions reported as having been treated successfully was also similar.

Intra-aortic balloon pump usage was higher in the femoral group and thrombus retrieval device use was higher in the transradial group. The majority of each group received adjunctive glycoprotein (GP) IIb-IIIa inhibitor therapy. The use of GP IIb-IIIa inhibitor therapy increased over the course of the study (GP IIb-IIIa use 89.8% vs 93.6% for procedure during first two years vs last two years respectively, p=0.026).

Primary and secondary outcomes

The main outcome data are presented in Table 3. There was no statistically significant difference in procedural success or major vascular complication rate between the two groups. Procedural success (accepting the cross-over rate) was achieved in the majority of patients regardless of initial access strategy. Major vascular complications were also similar between the two groups. However, all three complications recorded with an initial radial access strategy were related to subsequent femoral arterial access following crossover due to failure of the initial radial access strategy (2 cases of haematoma formation delaying discharge and 1 case of false aneurysm formation, requiring treatment with thrombin injection). When the analysis was repeated stratifying by the site of arterial complication rather than on the basis of initial access site, the rate of vascular complication was significantly higher at the femoral access site (0% vs 1.9% for radial vs femoral, p=0.001). Minor vascular complications were not significantly different between the groups. Failure of the initial access strategy was significantly more frequent with a radial approach compared to a femoral approach (7.7% vs 0.6% respectively, p<0.001).

Table 3. Primary and secondary outcomes.

Outcome	Radial approach, n=571	Femoral Approach, n=480	p value
Procedural success, n (%)	515 (92.1)	425 (89.9)	0.201
Major vascular complication, n (%)	3 (0.5)	6 (1.3)	0.315
Minor vascular complication, n (%)	10 (1.8)	12 (2.5)	0.398
Failed initial access strategy, n (%)	44 (7.7)	3 (0.6)	<0.001*
In-hospital mortality, n (%)	7 (1.2)	13 (2.7)	0.111
In-hospital MACCE, n (%)	15 (2.6)	25 (5.2)	0.029
Dual access required, n (%)	61 (10.7)	15 (3.1)	<0.001*
Needle-to-balloon time, minutes	17 (13-22)	17 (12-23)	0.188
Door-to-balloon time, minutes	46 (30-73)	67 (40-104)	<0.001*

Symptom-to-balloon time, minutes	183 (131-279)	211 (143-305)	0.003*
Contrast volume used, mls	210 (170-273)	240 (200-300)	<0.001*
Radiation dose absorbed, Gy/cm^2	25 (15-37)	32 (20-49)	<0.001*
Time to discharge, days	2.46 (1.60-3.83)	3.51 (2.36-6.07)	<0.001*

MACCE, major adverse cardiac or cerebrovascular event. Data presented as median (interquartile range) unless otherwise indicated. * remains significant at p<0.05 level after Bonferroni correction for multiple comparisons

In-hospital mortality and MACCE rates in the femoral group were approximately double that recorded in the radial group, although these differences were not statistically significant after Bonferroni correction. An initial radial access strategy did not have a significant impact on median needle-to-balloon times (17 minutes vs 17 minutes for radial vs femoral, p=0.188). However, median symptom onset-to-balloon and door-to-balloon times were significantly shorter in the radial group. The median volume of contrast used during the procedure was lower in the radial group as was radiation dose absorbed by the patient. The median length of stay following the procedure was also significantly shorter in the radial group (2.46 days vs 3.51 days for radial vs femoral, p<0.001). Discharge within 4 days of the procedure was achieved in 76.0% of the patients in the radial group compared with 57.2% in the femoral group (p<0.001).

Over the course of the study there was a fall in radiation dosage and contrast volume used (36 Gy/cm^2 vs 24 Gy/cm^2, p<0.001, and 230 mls vs 220 mls, p=0.007, for procedure in first 2 years vs last 2 years respectively). The differences between access groups in radiation dosage and contrast volume used were not significant after adjustment for study time period and other significant predictors, but the effect of radial access on length of stay remained significantly different (2.80 days vs 3.59 days for radial vs femoral, p<0.001. Full data available on request).

Regression analysis of primary outcomes

(a) Procedural failure. The independent predictors of procedural failure were age, serum creatinine concentration and procedure performed by operators other than operator 2. Compared to patients under the age of 65 years, those subjects aged 65 to 74 years and those aged 75 years or over had odds ratios (OR) of procedural failure of 1.78 (95% confidence intervals [CI] 1.01-3.08, p=0.044), and 2.91 (95% CI 1.69-5.00, p<0.001) respectively. Serum creatinine greater than 120 μmol/L was associated with a greater risk of procedural failure (OR 1.85, 95% CI 1.09-3.15, p=0.024). Operator 2 had a lower risk of procedural failure compared to the remaining operators (OR 0.36, 95% CI 0.18-0.71, p=0.003). After adjustment for these independent predictors, the relationship between initial access strategy and procedural failure remained non-significant (OR for procedural failure with radial approach 1.10, 95% CI 0.69-1.74, p=0.686).

(b) Major vascular complication. The main independent predictor of major vascular complication was a failure of the initial access strategy (OR 33.8, 95% CI 5.3-216.3, p<0.001). After adjustment for this, the effect of initial access strategy became significant, with a lower risk of major vascular complication in the radial group (OR 0.14, 95% CI 0.02-0.87, p=0.035).

(c) Failure by initial access site. The initial transradial approach was an independent predictor of this outcome (OR 19.8, 95% CI 5.75-68.3, p<0.001); the others were age of over 75 years (OR 3.39, 95% CI 1.79-6.44, p<0.001), operator 3 (OR 2.98, 95% CI 1.52-5.85, p=0.002) and operator 4 (OR 2.62, 95% CI 1.03-6.67, p=0.043).

DISCUSSION

Vascular access site complications remain a significant source of morbidity and possibly mortality following percutaneous coronary intervention,[19, 20] particularly in the current era with aggressive pharmacotherapy to inhibit platelet aggregation and protect against early stent thrombosis. This is of particular importance in the setting of primary PCI for acute ST elevation myocardial infarction where the treatment strategy usually includes the use of platelet glycoprotein IIb-IIIa antagonists.

Meta-analysis of coronary procedures performed via the radial and femoral arteries in the elective setting has previously shown the radial approach to be a safe alternative to the femoral approach with a lower risk of vascular complications.[21] However, in this meta-analysis, a radial approach was associated with a higher rate of procedural failure overall (OR 3.30, 95% CI 1.63-6.71, p<0.001). Previous small studies in the emergent setting of PPCI for acute STEMI have also shown lower vascular complication rates, but also similar procedural success when using the radial artery as access.[9, 14, 22-28] The results of the current study agree with the previously published literature. We found that procedural success (defined as TIMI 3 flow and less than 30% residual target lesion stenosis) was achievable in the majority of patients, irrespective of initial access strategy (92.1% vs 89.9% for radial vs femoral approach, p=0.201).

When the major vascular complications data were analysed on an intention-to-treat basis, there was no difference observed in complication rate between the groups (see Table 3). However, when our data were analysed by the site of vascular complication, there were no major complications associated with the radial artery puncture/cannulation. All three vascular complications in the initial radial strategy group were related to femoral vascular access. This finding is consistent with the majority of published data, where use of the radial artery as the access route has usually been associated with significantly lower (and often zero) major vascular complications.[9, 14, 22, 23, 24, 26, 27, 28]

In the first randomised comparison of elective PCI via the radial, brachial or femoral approaches, Kiemeneij *et al*[29] found similar procedural success regardless of strategy but a significantly lower risk of access site complications in the radial group (no complications in radial group compared with 2.3% and 2.0% in the brachial and femoral groups, p=0.035). However, the results of a randomised trial only reflect possible differences in outcomes in cases where an operator is equally happy to perform the procedure from either route. In reality, as our analysis shows, no operator is likely to perform all cases from the radial or femoral route. When evaluating an unselected series of consecutive cases, those factors that contribute to the reasons why a particular route is selected have to be taken into account when analysing the influence of access site on outcomes. In the PPCI setting the largest single centre study assessing safety of transradial PPCI by Valsecchi *et al*[14] experienced no major bleeding complications in 163 patients with STEMI treated via the radial

approach. Our analysis adds to the body of evidence in a much larger cohort of patients.

Logistic regression analysis identified age, serum creatinine concentration and procedure performed by operators other than operator 2 as independent predictors of procedural failure, and failure of the initial access strategy as the only independent predictor of major vascular complication. Older patients are more likely to have complex and calcified coronary artery disease, and so the impact of age on procedural success is understandable. Renal impairment has also been shown to be associated with lower procedural success.[30] With respect to some vascular complications, the effect of failed initial access strategy is to be anticipated as inability to cleanly puncture the access artery or multiple puncture attempts (as might occur during a failed access attempt) will increase the risk of vascular complication. An alternative explanation might be that a proportion of patients with a failed initial radial access strategy will already have received heparin (such as when cross-over occurs after the sheath has been inserted and heparin given), increasing this potential effect.

It is well recognised that there is a higher rate of initial access failure with a radial versus a femoral strategy in percutaneous coronary intervention.[7, 9, 14, 23, 27, 28] This is confirmed in our study and was comparable in frequency to previous studies. The most significant predictor of failure of initial access in our study, after radial access, was patient age. Previous studies have identified increased frequency of radial artery tortuosity and anomalies in older patients contributing to failed access.[31, 32]

In-hospital mortality and MACCE were similar between the radial and femoral access groups. It is reassuring that undertaking PPCI via a radial approach does not negatively influence the overall outcome and this is consistent with previously published data.[26] Our analysis is, however, limited by the relatively small number of events observed (20 deaths and 40 MACCE in the combined cohort).

The time from local anaesthetic administration to first balloon inflation or device used (the ‘needle-to-balloon’ time, corresponding to the reperfusion time) is a good measure of access equivalency, as it includes the time it takes to puncture the artery, but also encompasses any difficulties that may be encountered in accessing the aortic root, intubating the coronary arteries and delivering therapeutic devices. In the current study reperfusion times were similar between the groups (median of 17 minutes for each approach). Failed initial access strategy was also found to be an independent predictor of delayed reperfusion in this study (16.5 [95% CI 16.0-17.1] vs 29.4 [95% CI 25.0-34.5] minutes for successful vs failed initial access strategy, $p<0.001$).

Door-to-balloon and symptom-to-balloon times were both shorter in the radial access group. This is in contrast to the needle-to-balloon times, which were similar between the groups. Over the course of the study, significant changes were made to streamline the transfer process of patients from the site of their “call for help” to the catheter laboratory. These changes led to a reduction in the door and symptom times, and when coupled with the increasing preference for radial access (see Figure 1), explain this discrepancy.

Similarly, the increased use of thrombus extraction devices in the radial group is explained by the effect of increasing radial preference over time. Publication of the Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study[33] led to an increased use of these devices during PPCI in the latter stages of our study, with subsequent higher frequency in the radial group. The trends

towards lower mortality and MACCE rates in the transradial group of our study (Table 3) may reflect reductions in door-to-balloon times and the increased use of thrombus extraction devices over time.

In the context of primary PCI for STEMI, length of hospital stay following the procedure has been shown to be shorter in patients treated via a radial approach by a number of investigators.[14, 23, 24] This has a number of important implications with regard to cost of each patient admission, and increased bed turnover. In the current study we found patients treated with transradial PPCI to need a hospital stay 1 day shorter than those treated by the transfemoral route ($p<0.001$, see Table 3). This difference may be accounted for by early mobilisation in the radial group, but could also reflect a degree of selection bias against femoral access.

Minimising use of radiographic contrast remains a priority in the acute MI setting as these patients are at higher risk of contrast-related complications such as nephropathy and acute pulmonary oedema.[34] Higher volumes of contrast used during PPCI have also been associated with increased mortality.[35] Previous studies have shown that the volume of contrast used during PPCI via the transradial approach is similar to the volume used in the transfemoral approach.[22, 26, 27] Conversely, patients undergoing PPCI via the radial approach in the current study received 30 mls less contrast than those treated via the femoral approach ($p<0.001$). However, after adjustment for other significant predictors of contrast use, the effect of access strategy became non-significant.

Reducing radiation exposure to the patient, operator and catheter laboratory staff remains an important consideration during any procedure or technique that requires the use of X-ray. In this study, dose-area product was used as a surrogate for radiation exposure to the patient, and is superior to screening time as it more accurately reflects overall dosage, being affected by patient characteristics such as BMI and operating techniques.[36] In the current study, use of a radial access strategy was associated with a reduction in patient radiation exposure in the univariate analysis but after adjustment for other significant covariates, the difference was non-significant.

Study limitations

The main limitation of this study is that it might suffer from bias related to its non-randomised, retrospective design. In order to increase the robustness of the data presented, multiple regression analyses were performed to adjust for potential confounders and bias. Despite this, the validity of the results could be impaired by any factors that may affect outcomes and which were not recorded and included in the regression analyses. Heparin dose was not standardised across all operators, or between access strategies, and this may also have introduced bias into the results. The use of radial access increased over the course of the study and therefore may include a learning curve for some operators, in addition to introducing potential interaction effects (such as those observed in thrombus extraction device use, door- and symptom-to-balloon times). However, date of the procedure within the study period was not found to have an independent effect on the primary outcomes, nor did it substantially alter the effects of the other independent predictors when included in the final regression models. As patients with cardiogenic shock and those undergoing rescue PCI for failed thrombolysis were excluded from the study, the results should not be extrapolated to these groups of patients.

CONCLUSIONS

Primary angioplasty via the radial artery is a safe and effective alternative to the femoral approach in acute ST-segment elevation myocardial infarction without cardiogenic shock, with no adverse effect upon outcomes including in-hospital mortality and MACCE. No major vascular complications were experienced at the radial access site. However, failure to complete the procedure via the initial access strategy was more common with the radial approach, and was associated with increased needle-to-balloon times. Failure of initial access also occurs more frequently in the over 75 years age group. Uncomplicated transradial primary PCI is associated with reduced hospital length of stay.

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COMPETING INTERESTS

No competing or conflicting interests to declare.

FIGURE LEGEND

Figure 1. Change in volume (%) of transradial and transfemoral PPCI over the study period.

REFERENCES

1 Keeley EC, Boura JA, Grines CL. Primary angioplasty versus intravenous thrombolytic therapy for acute myocardial infarction: a quantitative review of 23 randomised trials. *Lancet.* 2003;**361**(9351):13-20.

2 Aguirre FV, Topol EJ, Ferguson JJ, *et al.* Bleeding complications with the chimeric antibody to platelet glycoprotein IIb/IIIa integrin in patients undergoing percutaneous coronary intervention. EPIC Investigators. *Circulation.* 1995;**91**(12):2882-90.

3 The EPIC Investigators. Use of a monoclonal antibody directed against the platelet glycoprotein IIb/IIIa receptor in high-risk coronary angioplasty. The EPIC Investigation. *N Engl J Med.* 1994;**330**(14):956-61.

4 Kinnaird TD, Stabile E, Mintz GS, *et al.* Incidence, predictors, and prognostic implications of bleeding and blood transfusion following percutaneous coronary interventions. *Am J Cardiol.* 2003;**92**(8):930-5.

5 Eichhofer J, Horlick E, Ivanov J, *et al.* Decreased complication rates using the transradial compared to the transfemoral approach in percutaneous coronary intervention in the era of routine stenting and glycoprotein platelet IIb/IIIa inhibitor use: a large single-center experience. *Am Heart J.* 2008;**156** (5):864-70.

6 Jolly SS, Amlani S, Hamon M, *et al.* Radial versus femoral access for coronary angiography or intervention and the impact on major bleeding and ischemic events: a systematic review and meta-analysis of randomized trials. *Am Heart J.* 2009; **157**(1):132-40.

7 Kassam S, Cantor WJ, Patel D, *et al.* Radial versus femoral access for rescue percutaneous coronary intervention with adjuvant glycoprotein IIb/IIIa inhibitor use. *Can J Cardiol.* 2004;**20**(14):1439-42.

8 Kim MH, Cha KS, Kim HJ, *et al.* Primary stenting for acute myocardial infarction via the transradial approach: a safe and useful alternative to the transfemoral approach. *J Invasive Cardiol.* 2000;**12**(6):292-6.

9 Louvard Y, Ludwig J, Lefevre T, *et al.* Transradial approach for coronary angioplasty in the setting of acute myocardial infarction: a dual-center registry. *Catheter Cardiovasc Interv.* 2002;**55**(2):206-11.

10 Mathias DW, Bigler L. Transradial coronary angioplasty and stent implantation in acute myocardial infarction: initial experience. *J Invasive Cardiol.* 2000;**12**(11):547-9.

11 Mulukutla SR, Cohen HA. Feasibility and efficacy of transradial access for coronary interventions in patients with acute myocardial infarction. *Catheter Cardiovasc Interv.* 2002;**57**(2):167-71.

12 Ochiai M, Isshiki T, Toyoizumi H, *et al.* Efficacy of transradial primary stenting in patients with acute myocardial infarction. *Am J Cardiol.* 1999;**83**(6):966-8, A10.

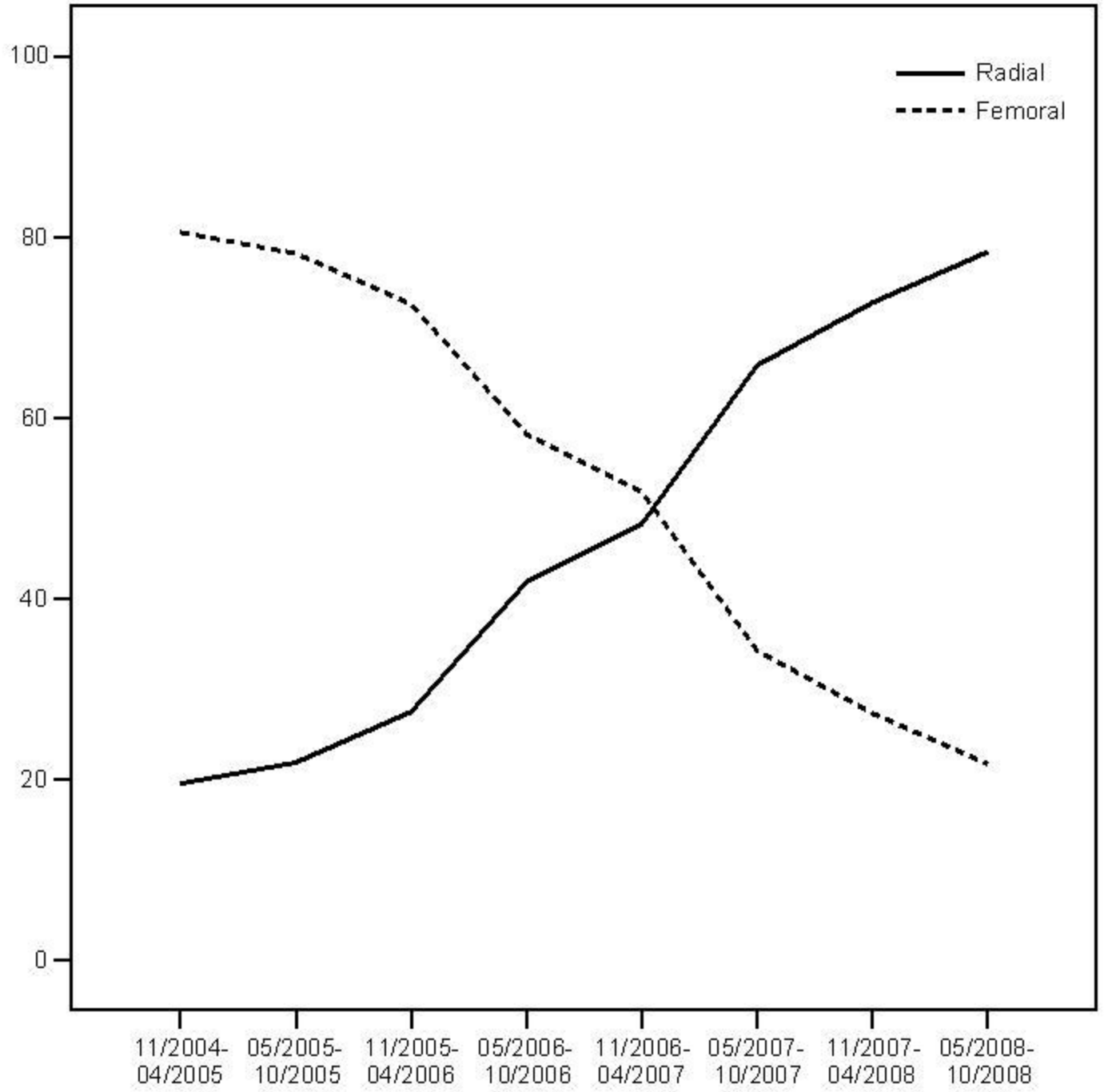
13 Steg G, Aubry P. Radial access for primary PTCA in patients with acute myocardial infarction and contraindication or impossible femoral access. *Cathet Cardiovasc Diagn.* 1996;**39**(4):424-6.

14 Valsecchi O, Musumeci G, Vassileva A, *et al.* Safety, feasibility and efficacy of transradial primary angioplasty in patients with acute myocardial infarction. *Ital Heart J.* 2003;**4**(5):329-34.

15 Ziakas A, Klinke P, Mildenberger R, *et al.* Comparison of the radial and the femoral approaches in percutaneous coronary intervention for acute myocardial infarction. *Am J Cardiol.* 2003;**91**(5):598-600.

16 Pristipino C, Trani C, Nazzaro MS, *et al.* Major improvement of percutaneous cardiovascular procedure outcomes with radial artery catheterisation: results from the PREVAIL study. *Heart.* 2009;**95**(6):476-82.
17 Jones RH, Kesler K, Phillips HR, III, *et al.* Long-term survival benefits of coronary artery bypass grafting and percutaneous transluminal angioplasty in patients with coronary artery disease. *J Thorac Cardiovasc Surg.* 1996;**111**(5):1013-25.
18 Smith LR, Harrell FE, Jr., Rankin JS, *et al.* Determinants of early versus late cardiac death in patients undergoing coronary artery bypass graft surgery. *Circulation.* 1991;**84**(5 Suppl):III245-III253.
19 Chase AJ, Fretz EB, Warburton WP, *et al.* Association of the arterial access site at angioplasty with transfusion and mortality: the M.O.R.T.A.L study (Mortality benefit Of Reduced Transfusion after percutaneous coronary intervention via the Arm or Leg). *Heart.* 2008;**94**(8):1019-25.
20 Montalescot G, Ongen Z, Guindy R, *et al.* Predictors of outcome in patients undergoing PCI. Results of the RIVIERA study. *Int J Cardiol.* 2007.
21 Agostoni P, Biondi-Zoccai GG, de Benedictis ML, *et al.* Radial versus femoral approach for percutaneous coronary diagnostic and interventional procedures; Systematic overview and meta-analysis of randomized trials. *J Am Coll Cardiol.* 2004;**44**(2):349-56.
22 Cantor WJ, Puley G, Natarajan MK, *et al.* Radial versus femoral access for emergent percutaneous coronary intervention with adjunct glycoprotein IIb/IIIa inhibition in acute myocardial infarction--the RADIAL-AMI pilot randomized trial. *Am Heart J.* 2005;**150**(3):543-9.
23 Kim JY, Yoon J, Jung HS, *et al.* Feasibility of the radial artery as a vascular access route in performing primary percutaneous coronary intervention. *Yonsei Med J.* 2005;**46**(4):503-10.
24 Philippe F, Larrazet F, Meziane T, *et al.* Comparison of transradial vs. transfemoral approach in the treatment of acute myocardial infarction with primary angioplasty and abciximab. *Catheter Cardiovasc Interv.* 2004;**61**(1):67-73.
25 Ranjan A, Patel TM, Shah SC, *et al.* Transradial primary angioplasty and stenting in Indian patients with acute myocardial infarction: acute results and 6-month follow-up. *Indian Heart J.* 2005;**57**(6):681-7.
26 Saito S, Tanaka S, Hiroe Y, *et al.* Comparative study on transradial approach vs. transfemoral approach in primary stent implantation for patients with acute myocardial infarction: results of the test for myocardial infarction by prospective unicenter randomization for access sites (TEMPURA) trial. *Catheter Cardiovasc Interv.* 2003;**59**(1):26-33.
27 Ziakas A, Gomma A, McDonald J, *et al.* A comparison of the radial and the femoral approaches in primary or rescue percutaneous coronary intervention for acute myocardial infarction in the elderly. *Acute Card Care.* 2007;**9**(2):93-6.
28 Brasselet C, Tassan S, Nazeyrollas P, *et al.* Randomised comparison of femoral versus radial approach for percutaneous coronary intervention using abciximab in acute myocardial infarction: results of the FARMI trial. *Heart.* 2007;**93**(12):1556-61.
29 Kiemeneij F, Laarman GJ, Odekerken D, *et al.* A randomized comparison of percutaneous transluminal coronary angioplasty by the radial, brachial and femoral approaches: the access study. *J Am Coll Cardiol.* 1997;**29**(6):1269-75.

30 Rubenstein MH, Harrell LC, Sheynberg BV, *et al.* Are patients with renal failure good candidates for percutaneous coronary revascularization in the new device era? *Circulation.* 2000;**102**(24):2966-72.
31 Lo TS, Nolan J, Fountzopoulos E, *et al.* Radial artery anomaly and its influence on transradial coronary procedural outcome. *Heart.* 2009;**95**(5):410-5.
32 Yoo BS, Yoon J, Ko JY, *et al.* Anatomical consideration of the radial artery for transradial coronary procedures: arterial diameter, branching anomaly and vessel tortuosity. *Int J Cardiol.* 2005;**101**(3):421-7.
33 Svilaas T, Vlaar PJ, van dH, I, *et al.* Thrombus aspiration during primary percutaneous coronary intervention. *N Engl J Med.* 2008;**358**(6):557-67.
34 Marenzi G, Lauri G, Assanelli E, *et al.* Contrast-induced nephropathy in patients undergoing primary angioplasty for acute myocardial infarction. *J Am Coll Cardiol.* 2004;**44**(9):1780-5.
35 Marenzi G, Assanelli E, Campodonico J, *et al.* Contrast volume during primary percutaneous coronary intervention and subsequent contrast-induced nephropathy and mortality. *Ann Intern Med.* 2009;**150**(3):170-7.
36 Geise RA, O'Dea TJ. Radiation dose in interventional fluoroscopic procedures. *Appl Radiat Isot.* 1999;**50**(1):173-84.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10/2007
11/2007-
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Heart

Primary percutaneous coronary intervention for acute ST-segment elevation myocardial infarction - changing patterns of vascular access, radial versus femoral artery.

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