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ORIGINAL ARTICLE

Routine use of fluoroscopic guidance and up-front femoral angiography results in reduced femoral complications in patients undergoing coronary angiographic procedures: an observational study using an Interrupted Time-Series analysis

Emily V. Castle[1] · Krishnaraj S. Rathod[1,2] · Oliver P. Guttmann[1] · Alice M. Jenkins[1] · Carmel D. McCarthy[1] · Charles J. Knight[1,2] · Constantinos O'Mahony[1] · Anthony Mathur[1,2] · Elliot J. Smith[1,2] · Roshan Weerackody[1,2] · Adam D. Timmis[1,2] · Andrew Wragg[1,2] · Daniel A. Jones[1,2]

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Abstract

Transradial access is increasingly used for coronary angiography and percutaneous coronary intervention, however, femoral access remains necessary for numerous procedures, including complex high-risk interventions, structural procedures, and procedures involving mechanical circulatory support. Optimising the safety of this approach is crucial to minimize costly and potentially life-threatening complications. We initiated a quality improvement project recommending routine fluoroscopic guidance (femoral head), and upfront femoral angiography should be performed to assess for location and immediate complications. We assessed the effect of these measures on the rate of vascular complications. Data were collected prospectively on 4534 consecutive patients undergoing femoral coronary angiographic procedures from 2015 to 2017. The primary end-point was any access complication. Outcomes were compared pre and post introduction including the use of an Interrupted Time-Series (ITS) analysis. 1890 patients underwent angiography prior to the introduction of routine fluoroscopy and upfront femoral angiography and 2644 post. All operators adopted these approaches. Baseline characteristics, including large sheath use, anticoagulant use and PCI rates were similar between the 2 groups. Fluoroscopy-enabled punctures were made in the 'safe zone' in over 91% of cases and upfront femoral angiography resulted in management changes i.e. procedural abandonment prior to heparin administration in 21 patients (1.1%). ITS analysis demonstrated evidence of a reduction in femoral complication rates after the introduction of the intervention, which was over and above the existing trend before the introduction (40% decrease RR 0.58; 95% CI: 0.25–0.87; $P < 0.01$). Overall these quality improvement measures were associated with a significantly lower incidence of access site complications (0.9% vs. 2.0%, $P < 0.001$). Routine fluoroscopy guided vascular access and upfront femoral angiography prior to anticoagulation leads to lower vascular complication rates. Thus, study shows that femoral intervention can be performed safely with very low access-related complication rates when fluoroscopic guidance and upfront angiography is used to obtain femoral arterial access.

Keywords Femoral access · Femoral angiography · Percutaneous coronary intervention · Fluoroscopy

Introduction

Vascular access complications after coronary angiography and percutaneous coronary intervention (PCI) increase morbidity, prolong hospitalization and raise hospital costs [1]. Although rates of radial artery access are increasing [2], there remain patients who cannot be accessed which, coupled with an increasing need for larger bore catheters (CTO and haemodynamic support) and structural intervention (TAVI), ensures a persistent requirement for catheterisation

✉ Daniel A. Jones
daniel.jones@qmul.ac.uk

[1] Barts Interventional Group, Interventional Cardiology, Barts Heart Centre, St Bartholomew's Hospital, 2nd Floor, King George V Building, West Smithfield, London EC1A 7BE, UK

[2] Department of Clinical Pharmacology, William Harvey Research Institute, Queen Mary University, London, UK

by the femoral approach. There is now a new generation of operators schooled in the radial approach whose inexperience in performing femoral punctures has the potential to increase the risk of complications [3, 4]. Measures to ensure the continued safety of the femoral access route are, therefore, vital with expertise in both femoral and radial artery access essential for contemporary interventional cardiologists [5–7].

Optimising the location of the anatomical puncture site is the most crucial factor in minimizing arterial complication rates [8]. At our institution we had a number of serious incidents resulting in severe patient harm due to high/low punctures or dissection related bleeding that could have been possibly avoided or managed in a more timely manner if diagnosed earlier. Therefore, to minimize and reduce femoral complication rates, a quality improvement project was initiated which recommended that routine fluoroscopic guidance (femoral head), and upfront femoral angiography should be performed post sheath insertion to assess for location and immediate complications. We examined the introduction of these measures to determine whether the rate of vascular complications had reduced. In view of the significant risk of bias inherent in observational studies we used an Interrupted Time-Series (ITS) analysis. ITS is a quasi-experimental methodology used to investigate the longitudinal effects of interventions [9, 10] and has been used for the evaluation of a wide range of public health interventions [11, 12].

Methods

Study design and patient population

This was a prospectively collected, observational study of 18,736 angiographic procedures from Barts Heart Centre, London UK. The data were collected over a 30-month period, from May 2015 to October 2017 and patients with stable angina or acute coronary syndromes undergoing coronary angiography were included. Patients undergoing multiple femoral procedures pre and post intervention were excluded. Of these 4534 (24.2%) underwent the procedure via the femoral approach and constituted the study population Fig. 1.

Ethics

Data were collected as part of a national cardiac audit and all patient identifiable fields were removed prior to analysis. The local ethics committee advised that formal approval was not required.

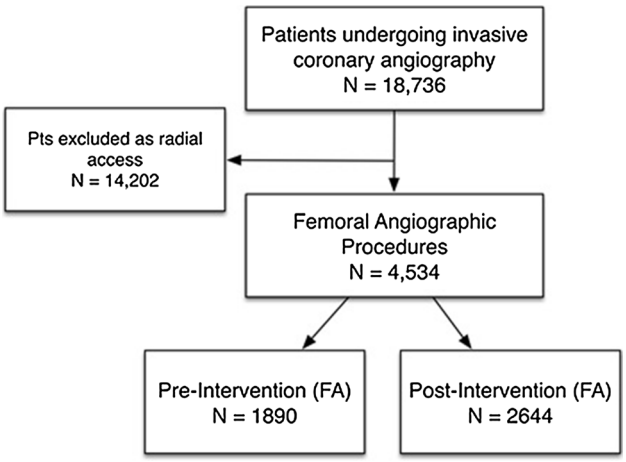

Fig. 1 Flow diagram of patients undergoing coronary angiography during the study period

Intervention

This study aimed to assess the impact of an intervention on femoral complication rates, introduced in mid-2016 following the first 12 months of the study. This intervention was a mandatory policy change at our institution meaning all operators changed their practice to follow the new approach. Pre-intervention, femoral access was performed as per operator preference (either with or without fluoroscopy femoral head guidance) and femoral angiography at the end of the case. The intervention mandated routine fluoroscopic screening of the femoral head (e.g., with scissors) to mark out the "safe zone" (Fig. 2) in the mid-point of the femoral head prior to sheath insertion. Immediately after sheath placement, an angiogram was performed to display sheath placement in 30°LAO (for left-sided punctures) and 30°RAO (for right-sided punctures), further images in different projections were used if the operator was unhappy with image quality, however, this was at operator discretion. Patients were divided into 2 groups, pre-and post the introduction of the femoral intervention. During the whole study period ultrasound guidance was available to all operators and used as per operator preference.

Procedural details

The procedures were a selection of diagnostic coronary angiography, where patients were not anticoagulated and percutaneous coronary intervention (PCI), where patients received activated clotting time (ACT)-guided heparin administration. In the pre-intervention group this was given prior to femoral angiography, however, in the

Fig. 2 Femoral anatomy (safe zone). **a** The black line defines the ideal puncture site located in the mid third of the femoral head. **b** Femoral angiogram demonstrating puncture of the common femoral artery at the level of mid-femoral head

post-intervention group femoral angiography was performed prior to heparin administration (anticoagulation).

In those patients undergoing PCI, the interventional strategy was at the discretion of the operator, including the use of direct stenting, pre/post-dilatation, intravascular imaging, and use of ablative devices. All patients undergoing angiography or PCI received aspirin 300 mg and either clopidogrel 300 mg or 600 mg or ticagrelor 180 mg prior to the procedure. All patients undergoing PCI were prescribed 75 mg aspirin and 75 mg clopidogrel or 90 mg ticagrelor maintenance therapy. ADP receptor antagonist maintenance therapy was recommended for 1 month in the BMS group, 12 months in the DES group and 12 months for patients treated for STEACS/NSTEACS. In patients undergoing PCI, unfractionated heparin was given during the procedure at a loading dose of 70–100 U/kg with the ACT maintained>250 s. Glycoprotein IIb/IIIa inhibitors were used at the operator's discretion and according to local guidelines. For all non-emergent angiography anticoagulation (warfarin or NOAC) were stopped prior to the procedure, for emergent procedures they were performed on the therapy.

Data collection

Data were prospectively entered into a clinical angiogram and PCI database at the time of the procedure, with PCI data entered in accordance to the British Cardiovascular Intervention Society (BCIS) standards. Data collected included patient characteristics (age, prior Myocardial infarction (MI), percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG), hypertension, diabetes mellitus, hypercholesterolemia, smoking status, and cardiogenic shock) and procedure related data (indications for PCI, target vessel, number of diseased vessels, use of intravascular ultrasound (IVUS), optical coherence tomography (OCT), pressure wire, use of drug-eluting stent and GPIIb/IIIa inhibitor). Patients with femoral complications were identified from the angiography database and all available clinical/procedural records and angiograms were reviewed.

Endpoints

The primary end-point was any access complication, defined as: haematoma ≥5 cm, pseudoaneurysm formation, retroperitoneal hemorrhage, arterial dissection, vessel thrombosis, non-coronary artery bypass graft-related access bleeding requiring transfusion, access site infection, or hemoglobin drop of ≥3 g/dl with an access source or ≥4 g/dl with an unknown source.

Statistical analysis

Baseline patient, procedural, and post-procedural characteristics were compared between the 2 groups. Categorical data are summarized using absolute values (percentage). Normally distributed, continuous data are presented as mean ±SD or, where skewed, as median (25–75 percentile). Normally distributed continuous variables were compared using Student's *t* tests, and the Mann–Whitney *U* test was used to compare non-normally distributed continuous variables. Categorical data were compared using the Pearson's Chi-squared test.

To assess the effect of public reporting on outcomes two statistical approaches were used i.e., Interrupted Time-Series (ITS) analyzes and logistic regression. The main analysis performed was the ITS analyzes. This is a

useful quasi-experimental design with which to evaluate the longitudinal effects of interventions through regression modeling [9, 12] and has been used for the evaluation of a wide range of public health interventions [12]. For the non-randomized assessment of the impact of public reporting on outcome ITS in one of the most useful methods available [12]. Femoral complication rates (monthly) were analyzed using ITS to compare the periods before and after introduction of the intervention, adjusting for seasonality and long-term trends as is standard with the use of statistical tool [10]. Models were based on time-series of the rates for monthly PCI procedures. Standard methods for interrupted time-series were adopted to assess the impact of the intervention, the level and trend of the pre-intervention segment served as the control for the post-intervention segment. The difference between pre- and post-intervention slopes and the effect on femoral complications after its introduction were estimated. A two-sided $P < 0.05$ was considered statistically significant. All statistical analyzes were performed using STATA version 15.0 (StataCorp, College Station, TX).

Results

Over the 30-month study period 4534 patients underwent angiographic procedures from the femoral route. The commonest reason for a femoral approach was an unsuccessful radial attempt (45.2%), followed by the presence of previous CABG (19.7%). Additional reasons include larger sheath size and cardiogenic shock. Of the total cohort, the average age was 66.52, the average body mass index (BMI) was 29.16, with previous coronary artery bypass grafts (CABG) patients making up 19.3% of the population. Of these, 2644 received the intervention (Fluoroscopic screening and upfront femoral angiography (FA)) and 1890 did not. Following the introduction of the intervention all patients undergoing coronary angiography followed these measures as per departmental/institutional policy.

Baseline patient, presentation and procedural characteristics

The baseline demographics are presented in Table 1, including patient and procedural characteristics (anticoagulation,

Table 1 Baseline and Procedural Characteristics pre and post intervention (up-front fluoroscopy and femoral angiography)

	Pre ($n = 1890$)	Post ($n = 2644$)	P value
Patient characteristics			
Age (years)	66.31 ± 13.42	66.76 ± 11.51	0.4254
Female sex	437 (23.1)	603 (22.8)	0.2119
BMI	29.21 ± 5.42	29.10 ± 6.12	0.6750
Diabetes	455 (24.1%)	608 (23.0%)	0.2450
Hypertension	1270 (67.2%)	1727 (65.3%)	0.320
Hypercholesterolamia	1002 (53.0%)	1478 (55.9%)	0.410
Previous MI	278 (14.7%)	452 (17.1%)	0.330
Previous CABG	380 (20.1%)	489 (18.5%)	0.153
Previous PCI	183 (9.7%)	270 (10.2%)	0.256
Previous cerebrovascular accident	66 (3.5%)	87 (3.3%)	0.320
Peripheral vascular disease	68 (3.6%)	114 (4.3%)	0.1732
Diagnostic angiogram only	970 (51.3%)	1378 (52.1%)	0.2450
Presentation			
Stable	936 (49.5%)	1274 (48.2%)	0.4250
ACS	663 (35.1%)	960 (36.3%)	
Primary PCI	291 (15.4%)	410 (15.5%)	
Cardiogenic shock	243 (12.9%)	320 (12.1%)	
Procedure characteristics			
Heparin administration	920 (49.7%)	1266 (47.9%)	0.1730
Sheath size	6.3 ± 0.6	6.1 ± 0.5	0.1530
Vascular closure device	1513 (80.1%)	2094 (79.2%)	0.2110
GPIIb/IIIa	338 (17.9%)	432 (16.5%)	0.3450
Operator experience			
Consultant	882 (45.7%)	1227 (46.4%)	0.322
Trainee	1008 (53.3%)	1417 (53.6%)	

sheath size, vascular closure device and GPIIb/IIIa use). No significant differences were seen between the two groups, pre and post the intervention. Importantly, rates of ultrasound guided femoral access were similar between the 2 groups (5.8% pre and 6.2% post, $P=0.710$) as were procedural durations (fluoroscopy time 9.5min vs 10.2min, $P=0.450$) and contrast doses (94.3 ± 32.6 ml vs 97.4 ± 21.3 ml, $P=350$).

Safe zone

Fluoroscopy-enabled punctures were made in the 'safe zone' in over 91% of cases after the introduction of upfront femoral angiography, compared to 86% ($P<0.001$) pre introduction. Aside from the introduction of mandated fluoroscopy (the intervention), the instance of punctures outside the safe zone were most likely due to individual differences in patient anatomy i.e., high femoral bifurcations with similar numbers seen in the 2 treatment groups (6.1% vs 5.8%, $P=0.820$).

Haemostasis

Methods of achieving haemostasis included the use of vascular closure devices such as Angioseal (83%), exoseal (2%) or pro-glide (1.0%) with the remaining cases achieved with manual pressure (14%). No differences in these rates were seen pre and post the introduction of the intervention.

Effect on complication rate

Complication rates were reduced overall from 2% to 0.9% ($P<0.001$) between the two groups (see Fig. 3). Upfront femoral angiography resulted in management changes in 21 patients (1.1%) with the procedure being abandoned prior to heparin administration, preventing potential complications. None of these patients undergoing early procedural abandonment required treatment other than conservative management (i.e., manual pressure and monitoring (± local ultrasound imaging). Of the complications recorded, 48% were recorded as haematomas requiring overnight stay, 14% were diagnosed retroperitoneal haematomas requiring no intervention, 24% were diagnosed retroperitoneal haematomas requiring intervention, defined as bleeding requiring transfusion, or referral to either vascular surgeons or vascular radiology, 8% were recorded dissections, 3% developed an ischaemic leg post-Angioseal and 3% of patients died as a result of femoral complications. The average length of stay was also significantly lower among patients in the intervention group (1.6 days vs. 2.3, $P<0.001$).

Time series analysis

The scatter plot of femoral complication rates over the study period is displayed in Fig. 4. ITS analysis demonstrated

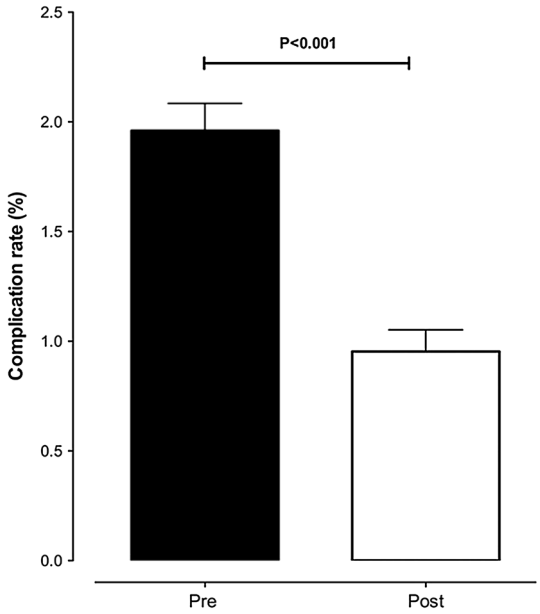

Fig. 3 Femoral complication rates pre and post Intervention. The bar chart shows a significant reduction in complication rates pre and post the introduction of the intervention. Comparison made using unpaired *t* test

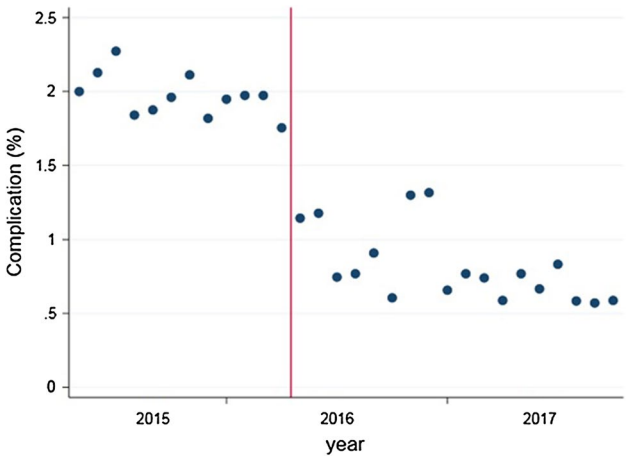

Fig. 4 Femoral complication rates following angiography by month Scatter plot of monthly complication rates (%) over time. Each dot represents the complication rate per month of study (%). Red line indicates the introduction of upfront femoral angiography and fluoroscopy

evidence of a reduction in femoral complication rates after the introduction of the intervention, which was over and above the existing trend before the introduction (40% decrease RR 0.58; 95% CI 0.25–0.87; $P<0.01$) (Fig. 5). The counterfactual line, i.e., the expected change in complication rates based on the time trend prior to the introduction of the intervention is also shown in Fig. 5 which clearly displays

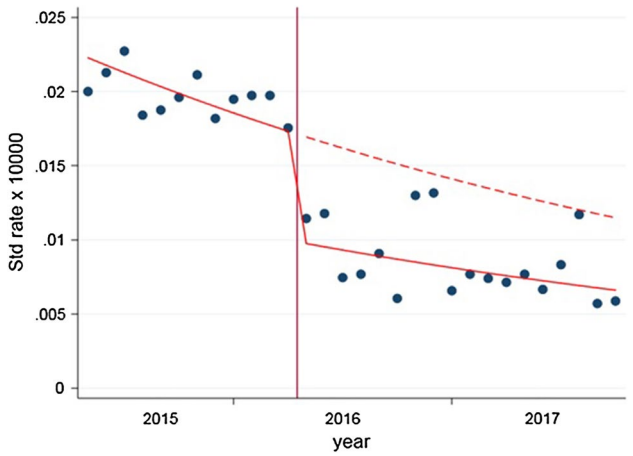

Fig. 5 Interrupted Time-Series of femoral complications after angiography with counterfactual line. Time series data with regression lines drawn for pre and post intervention periods (introduction indicated by red line). A level change is clearly demonstrated with the counterfactual (dotted red line) demonstrated

this significant slope change seen associated with the introduction ($P < 0.01$). The final model was run following correction for time (seasonal variations), over-dispersion was allowed for and adjustment made for autocorrelation with no differences seen in the effect.

Discussion

This large, observational registry of patients undergoing coronary angiographic procedures via the femoral approach highlights a simple, novel approach to reducing complication rates. Despite declining femoral access rates with a preference for the radial route, femoral vascular access-related complications remain a cause of morbidity and mortality and have a significant impact on long-term clinical outcomes. This easy-to-implement approach to femoral puncture with routine fluoroscopy and upfront femoral angiography adopted by all operators at our institution appears to be a successful way to reduce and minimize these complications.

In the radial era of coronary intervention, femoral arterial access although no longer the route of choice for the majority of cases is necessary to deal with the diversity of patients seen in practice. A recent international survey demonstrated significant variability still exists in preferences for femoral access technique [13] and despite recommendations for fluoroscopic and ultrasound guidance, alongside femoral angiography most operators use palpation alone, the 'palpate and stick' approach [14]. The lack of adoption of imaging guidance (either fluoroscopy or ultrasound) for vascular access deserves further investigation and this study clearly demonstrates that in a real world group of coronary interventionalists at a large tertiary center, that a simple algorithm followed appropriately leads to improved patient outcomes. Contrary to the descriptions of optimal femoral access from cardiovascular thought leaders and various society guidelines, the practice of femoral access in the real world appears suboptimal [13, 14]. This is, therefore, an important study, as it provides impetus for quality improvement to improve the use of techniques to enhance vascular access.

Declining femoral access rates

The current British Cardiovascular Intervention Society (BCIS) audit data clearly portrays an increase in the rates of radial artery access for coronary angiography and intervention in the UK, from 10.2% in 2004 to 80.5% in 2015 [2]. Consequently, the rates of femoral access are decreasing, leaving operators regularly performing, and becoming vastly more comfortable with radial punctures. The femoral artery carries large volumes of blood around the body and arguably requires a completely different skillset to puncture safely, in addition to the consequences of any complications associated with this artery vastly exceeding any of the radial artery [15]. Therefore, it is possible that an increase in the rates of femoral artery access complications may be seen in centers with high radial rates.

Anatomical placement and the safe zone

There are several factors which contribute to both the likelihood of a femoral complication occurring and its significance, including, anatomical sheath placement, anticoagulation and artery injury post sheath insertion. Anatomically correct sheath placement also correlates with rates of complication and, therefore, with rates of morbidity and mortality [16]. Research demonstrates a reliable relationship between the level of the common femoral artery and the femoral head, making it an ideal fluoroscopic puncture target [17], therefore, it is reasonable to suggest that the location of the femoral head prior to puncture will improve the safety of femoral punctures. This study clearly demonstrates this with the visualization of the femoral head prior to puncture, resulting 91% of punctures being made within the 'safe zone'. This is likely to be a contributor in the decrease in complication rates seen in this audit. Placement of the sheath within the 'safe zone' allows control of a patient's haemodynamics and is defined as within the common femoral artery, above the bifurcation and underneath the inferior epigastric artery [18]. An 'ideally' placed femoral sheath is seen in Fig. 2 with the puncture within the mid-portion of the femoral head, above the bifurcation and below the inguinal ligament [19]. Femoral punctures performed without prior imaging of the femoral head are often not achieved within the safe zone due to variations in patient anatomy and

particularly noted in patients with high BMI where anatomical landmarks are not obvious [20].

Changes in management

Maintaining a balance of anticoagulation risk plays a great part in femoral artery complications, therefore, it is natural to assume that in cases where a vascular complication is not recognized prior to heparin administration, consequences will far outweigh those where it was recognized earlier or at least prior to anticoagulation [21]. At our center, anticoagulation is managed using activated clotting time (ACT) with an aim to maintain an ACT of >250 s, during PCI to reduce thromboembolic complications [22]. This study saw changes in patient management in 1.1% of cases, specifically, 21 patients had abandoned procedures prior to heparin administration because of femoral artery injuries, which could have otherwise become major complications. These patients were kept for a short period post procedure at the discretion of the clinicians and re-booked for another occasion. This seemingly large number of patients indicates the efficacy of this technique in reducing what could have been potentially life-changing complications in these patients if anticoagulation was undertaken.

Reduction in overall complication rates

The aim of this quality improvement initiative was to reduce femoral artery access site complication rates at our institution, as has been discussed, this has been achieved by reducing overall complication rates by 1.1%. Though many techniques to reduce such complications are available, such as ACT optimization and ultrasound guided punctures (as demonstrated in the FAUST trial [18]), this intervention was deemed to be the simplest technique as it involved using fluoroscopy time that was already being used and changing the timing of it to the beginning rather than the end of the case. Although there is evidence for ultrasound guidance [18] being superior it is costly, currently has not been widely adopted and it can lead to a greater incidence of high punctures compared to fluoroscopic guidance [23], therefore, a simple pre-existing combination approach of real time fluoroscopic guidance and upfront femoral angiography can be easily implemented. This, therefore, gives a method where there was no extra equipment, radiation or contrast cost involved.

Limitations

The observational nature of this study may lead to confounding factors as is well known with this design it is also a single-site audit which has its own inherent limitations. It could also be argued that the improved rates of femoral complication were caused by an increased awareness by the operator of the risk of femoral complications and, therefore, and increase in the care taken when performing the femoral puncture.

Conclusion

Femoral artery access complications associated with coronary artery angiography is associated with increased morbidity and mortality and with operators potentially becoming less experienced at performing femoral puncture, solutions to reduce complication rates are required. This study has demonstrated a dramatic decrease in vascular access complication rates at our site (0.9%) in coronary artery angiography via the femoral approach, indicating a significant improvement in patient outcomes.

Conflict of interest All authors declare that they have no conflict of interest.

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