**Vascular access site and outcomes among 26,807 chronic total coronary occlusion angioplasty cases from the British Cardiovascular Interventions Society National database**

Tim Kinnairda, MD, Richard Andersona, MD, Nick-Ossei-Gerninga, MD, Sean Gallaghera, MD, Adrian Largeb, MD, Julian Strangec, MD, Peter Ludmand, MD, Mark deBeldere, MD, James Nolanb,g, MD, David Hildick-Smithf MD, and Mamas Mamasb,g, PhD. aDepartment of Cardiology, University Hospital of Wales, Cardiff, UK; bDepartment of Cardiology, Royal Stoke Hospital, UHNM, Stoke-on-Trent, UK; cDepartment of Cardiology, Bristol Royal Infirmary, Bristol, UK; dDepartment of Cardiology, Queen Elizabeth Hospital, Edgbaston, Birmingham, UK; eDepartment of Cardiology, The James Cook University Hospital, Middlesbrough, UK; fDepartment of Cardiology, Sussex Cardiac Centre, Brighton and Sussex University Hospitals, Brighton, UK; gKeele Cardiovascular Research Group, Institute of Applied Clinical Sciences, University of Keele, Stoke-on-Trent, UK.

**Corresponding Author:**

Dr. Tim Kinnaird

Consultant Interventional Cardiologist

Department of Cardiology,

University Hospital of Wales,

Cardiff, UK

Email: tim.Kinnaird2@wales.nhs.uk

Phone: +44 2920 743938

Fax: +44 2920 744473

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**Abstract**

**Background:** Given the influence of access site on outcomes, use of radial access in chronic total occlusion percutaneous coronary intervention (CTO-PCI) warrants further investigation. **Objectives:** Using a national PCI database, access site choice and outcomes after CTO-PCI were assessed. **Methods:** Data were analysed from the British Cardiovascular Intervention Society dataset on 26,807 elective CTO-PCI procedures performed in England and Wales between 2006 and 2013. Multivariate logistic regression was used to identify predictors of access site choice and its association with outcomes. **Results:** There was a significant decrease in femoral artery (FA) utilisation from 84.6% in 2006 to 57.9% in 2013. Procedural factors associated with FA access included dual access (odds ratio 3.89, 95% confidence intervals 3.45-4.32), Crossboss/Stingray (1.87, 1.43-2.12), intra-vascular ultrasound (1.32, 1.21-1.53), and micro-catheter use (1.18, 1.03-1.39). There was an association between FA access and the number of CTO devices used (p=0.001 for trend). An access site complication (1.5 vs. 0.5%, p<0.001), peri-procedural MI (0.5 vs. 0.2%, p=0.037), major bleeding (0.8 vs. 0.2%, p<0.001), transfusion (0.4 vs. 0%, p<0.001) and 30-day death (0.6 vs. 0.1%, p=0.002) were more frequent in patients undergoing CTO-PCI using femoral artery access. An access site complication during CTO-PCI was associated with significant increases in transfusion (8.0 vs. 0.1%, p<0.001), procedural coronary complication (17.3 vs. 5.8%, p<0.0001), major bleeding (8.4 vs. 0.3%, p<0.001) and mortality at all time points. **Conclusions:** Femoral artery access remains predominant during CTO-PCI with case complexity and device size associated with its use. Access site complications were more frequent with FA use and strongly correlated with adverse outcomes.

**Condensed abstract**

Using a national PCI database, access site choice and outcomes after CTO-PCI on 26,807 elective CTO-PCI procedures performed in England and Wales between 2006 and 2013. There was a significant decrease in femoral artery (FA) utilisation from 84.6% in 2006 to 57.9% in 2013. Procedural factors associated with FA access included dual access, Crossboss/Stingray, intra-vascular ultrasound and micro-catheter use. There was an association between FA access and the number of CTO devices used. An access site complication, peri-procedural MI, major bleeding, transfusion and 30-day death were more frequent in patients undergoing CTO-PCI using femoral artery access.

**Keywords**

Access choice, chronic total occlusion, percutaneous coronary intervention, complications, national database

**Abbreviations**

BCIS - British Cardiovascular Intervention Society

CABG – Coronary artery bypass surgery

CCS- Canadian Cardiovascular Society

CTO - Chronic total occlusion

MI - Myocardial infarction

NICOR - The National Institute of Cardiovascular Outcomes Research

NYHA – New York Heart Association

OR - Odds ratio

PCI - Percutaneous coronary intervention

**Introduction**

Radial arterial access is increasingly the preferred choice for percutaneous coronary intervention (PCI) among interventional cardiologists worldwide.1-2 Factors influencing this major change in practice over the last decade include an improvement in patients’ experience, a reduction in hospital costs through facilitation of day-case PCI,the avoidance of major bleeding, transfusion and access site complications and a reduction in short and long-term mortality.3-10 Although there remains a significant variation in radial rates by country, centre and operator, many default radial centers now perform over 90% of procedures without the need to puncture the femoral artery. Indeed, the most recent British Cardiovascular Intervention Society (BCIS) National Angioplasty Audit revealed that in 2014, 75.3% of all PCI procedures in the United Kingdom were performed using the radial artery.11

Access site choice is defined by a number of factors including physician practice and preference, anatomical variation (such as radial loops), radial occlusion and arterial spasm.12,13 However, particularly complex case sub-groups such those patients with a history of CABG and those with chronic occlusive disease may still be undertaken using femoral arterial access.14 In particular chronic total occlusion PCI (CTO-PCI) presents several access site challenges including the need for dual arterial access and large caliber guide catheters to facilitate CTO techniques.15,16 Therefore, moving to routine radial arterial access remains a technical challenge for many CTO-PCI procedures despite advances in the technology and experience that have facilitated the almost exclusive radial artery use in non CTO-PCI procedures in many centers.

CTO outcomes from the BCIS dataset has previously been analysed but without a specific focus on access site.17 There are many sources of data - both randomised and registry-based – on non CTO-PCI procedures and access site, but no clinical trials of access site practice in CTO-PCI and its associated outcomes and only limited observational registry data from small single centre series.18-20 Therefore, the aim of the present study was to examine using the BCIS National PCI Audit, the baseline demographics, procedural characteristics and predictors, and the outcomes of patients undergoing CTO-PCI from the femoral artery compared to the radial artery.

**Methods**

*Study design, setting and participants*

We analysed national data from all patients with stable angina who underwent elective percutaneous coronary intervention for chronic total occlusion intervention (CTO-PCI) in England and Wales between January 2006 and December 2013.

*Setting, data source, and study size*

Data on PCI practice in the United Kingdom were obtained from the British Cardiovascular Intervention Society (BCIS) dataset that records this information prospectively and publishes this information in the public domain as part of the national transparency agenda.21 The data collection process is overseen by The National Institute of Cardiovascular Outcomes Research (NICOR) (http://www.ucl.ac.uk/nicor/) with high levels of case ascertainment. In 2013, 98.6% of all PCI procedures performed in the National Health Service (NHS) hospitals in England and Wales (www.bcis.org.uk/) were recorded on the database. The BCIS-NICOR database contains 113 clinical, procedural and outcomes variables with approximately 80,000 new records added each year. The participants of the database are tracked by the Medical Research Information Services for subsequent mortality using the patients' NHS number (a unique identifier for any person registered within the NHS in England and Wales). Although the BCIS dataset is UK wide, only patients from England and Wales have mortality tracked by the Office of National Statistics, and so the current analysis is restricted to patients from these 2 countries only.

*Study definitions*

We analysed all recorded elective CTO-PCI procedures that were undertaken for stable angina in England and Wales between January 1st, 2006 and December 31st, 2013. Patients were categorised according to access site choice during CTO-PCI. Participants with missing information on access site and CTO status were excluded. In cases when more than one arterial access site was used, any femoral artery puncture was defined as a femoral case. For example, in a dual access case with left radial and right radial access this was considered a radial case. However, in a dual access case with right radial and right femoral access this was considered a femoral case. Study definitions were used as in the BCIS-NICOR database. Specifically, pre-procedural renal failure is defined as any one of the following: creatinine >200µmol/l, renal transplant history, or dialysis. Penetration catheters most commonly used during the study period were the Tornus® or Gopher® catheter. Micro-catheters most commonly used during the study period were the Corsair® or Finecross® catheter. An access site complication is defined as either a false aneurysm, haemorrhage (without haematoma). haemorrhage with delayed discharge, retroperitoneal haematoma, arterial dissection, or any access site complication requiring surgical repair. For the purposes of the current study we defined in-hospital major bleeding as either gastrointestinal bleed, intra-cerebral bleed, retroperitoneal hematoma, blood or platelet transfusion, or an arterial access site complication requiring surgery.

The clinical outcomes of interest were in-hospital death, 30-day mortality, 1-year mortality, in-hospital bleeding, peri-procedural infarction, emergency surgery, stroke, cardiac tamponade, side branch occlusion, slow flow, coronary dissection for which we initially calculated the crude rates by access site choice.

*Data analyses*

The rates of access site choice by year of PCI were analysed using linear regression. All study years (2006-13) are presented in this analysis. However, for the purposes of examining the predictors and outcomes of access site choice for CTO-PCI, analysis was restricted to the final two years of data (2012 and 2013) to encompass mature interventional practice and when changes in access choice rates were minimal. For these years, we examined the baseline characteristics of participants by access site. These variables included age, sex, smoking status, body mass index (BMI), family history of coronary heart disease, hypertension, hyperlipidaemia, diabetes, previous myocardial infarction, previous stroke, peripheral vascular disease, valvular heart disease, renal disease, previous PCI, previous CABG, left ventricular function, antiplatelet therapy, warfarin use, bivalirudin use, glycoprotein IIb/IIIa inhibitors use, vessel attempted for PCI (graft, left main, left anterior descending (LAD), circumflex, right coronary), radial access, stent implanted, rotational atherectomy use, laser angioplasty use, cutting balloon use, presence of a chronic occlusion, surgical cover, and year of PCI. We tested for associations between each categorical variable and access site using a Chi-squared test, and for continuous variables we used one-way analysis of variance. We then performed a multivariate analysis of the predictors of access site in 2012/13 using multivariate logistic regression to investigate the influence of variables that have the potential for being included in the linear component of a proportional hazard model. Variables included in the model were gender, CCS class, NHYA class, previous MI, previous CABG, previous PCI, diabetes, lesion location, imaging use, rotational atherectomy use, penetration catheter use, micro-catheter use, CrossBoss use and dual access. To correct for missing values, we first imputed missing data on baseline covariate using multiple imputations with chained equations to adjust for missing data (missing data points are presented in Supplemental Table 1). We then ran a stepwise forward selection with a proportional hazard model with p < 0.1 as entry criteria. In order to correct for a possible error during imputation that might be introduced by missing values being distributed in a non-random fashion, we used a pattern mixture model during sensitivity analysis. Finally, an individual logistic regression analysis was performed to investigate the impact of an arterial complication in the years 2012/13 on clinical outcomes.

**Results**

*Temporal trends and baseline demographics by access site choice for CTO-PCI*

Between 2006 and 2013, 26,807 stable angina CTO interventions were performed in the UK with significant increases in overall PCI and CTO-PCI numbers although the numbers of cases performed for CTO-PCI as a percentage of total PCI dropped significantly (Figure 1A). During the study period, there was a significant decrease in femoral artery utilisation from 84.6% in 2006 to 57.9% in 2013 (Figure 1B, p<0.0001) and although changes plateaued from 2011 onwards, femoral use remained dominant. Between 2006 and 2013, there was a significant increase in dual arterial access use (Figure 2B, p<0.0001). Within dual access cases, although there was a significant increase in dual access via radial use (0% to 6.6% during study period, p=0.0045), 93.4% of dual access cases were undertaken using at least one femoral puncture (Figure 2B). The baseline demographics by access site for patients undergoing CTO-PCI in 2012 and 2013 are presented in Table 1. In general, baseline clinical characteristics did not differ significantly by access site choice for CTO-PCI although a history of previous PCI and a history of previous CABG were the strongest associates,

*Procedural variables by access site choice for CTO-PCI*

The procedural variables for patients by access site are presented in Table 2. In contrast to patient baseline characteristics, there were many significant differences amongst procedural variables patients who under CTO-PCI using femoral artery access compared to those via radial artery access. Additionally, the complexity of the intervention was closely associated with access choice with a primary consultant operator, dual arterial access, intra-vascular ultrasound, rotational atherectomy, penetration catheter, micro-catheter, and Crossboss/Stingray use all more frequently observed when femoral artery access was chosen. There was a highly significant association between femoral artery access and the number of CTO devices used (R2=0.965, p=0.001 for trend, Figure 3A), and a highly significant association between dual arterial access and the number of CTO devices used (R2=0.996, p=0.0001 for trend, Figure 3B). Procedural success and the number of successful lesions was lower in the femoral cohort (Table 2). Supplementary table 2 illustrates baseline variables and procedural variable categorised by radial only, radial dual access, femoral only, radial/femoral dual access and femoral dual access.

*Predictors of access site choice for CTO-PCI*

Using multivariate analyses, covariates found to be associated with femoral artery access for CTO-PCI in 2012 and 2013 were identified and are presented in Table 3. The only patient-related factors associated with femoral access were female gender and a history of previous revascularisation. Procedural factors associated with femoral artery access were dual arterial access Crossboss/Stingray use, intra-vascular ultrasound use, rotational or laser atherectomy, and micro-catheter use. Circumflex CTO intervention was associated with lower use of femoral artery access.

*Clinical outcomes by access site choice for CTO-PCI*

Acute coronary arterial procedural complications for CTO-PCI procedures carried out in 2012 and 2013 were similar between the femoral and radial cohorts (Table 4). However, in-hospital complications including an access site complication (1.5 vs. 0.5%, p<0.001), peri-procedural MI (0.5 vs. 0.2%, p=0.037), major bleeding (0.8 vs. 0.2%, p<0.001), blood transfusion (0.4 vs. 0%, p<0.001) and death (0.2 vs. 0.1%, p=0.027) were more frequent in patients undergoing CTO-PCI using femoral artery access. Mortality at 30-days (0.6 vs. 0.1%, p=0.002) was greater in femoral cohort. Supplementary figure 1 illustrates outcomes categorised by radial only, radial dual access, femoral only, radial/femoral dual access and femoral dual access.

*Clinical outcomes by access site complication during CTO-PCI*

In an analysis of the full 2006-2013 cohort, a femoral access site complication during CTO-PCI was associated with significant increases in transfusion (8.0 vs. 0.1%, p<0.001), acute procedural coronary complication (17.3 vs. 5.8%, p<0.0001), major bleeding (8.4 vs. 0.3%, p<0.001) and mortality at all time points (Table 5). Using individual logistic regression, the adverse association of an arterial complication on clinical events was significant (Table 6). Figure 4 illustrates the Kaplan Meier plots for mortality by femoral access site complication status to 12-months confirming the significant relationship between this event on patient survival (p=0.001).

**Discussion**

The findings of the current study can be summarised as follows: 1) There was a significant increase during the study period in radial artery access for CTO-PCI, although the femoral artery remained the predominant access site; 2) Dual arterial access increased significantly during the study period and was driven mainly by femoral artery use; 3) Dual arterial access was closely correlated with procedure complexity; 4)The main predictors of femoral use were CTO-PCI procedure complexity; 5) Access site complications were significantly more likely in the femoral cohort; 6) Femoral access site complications were strongly predictive of adverse patient outcomes. The findings of the current study are largely consistent with previous studies although the totality of the evidence is limited to observational studies (largest series 950 cases) and a total of <4000 cases in a recent meta-analysis.18-20 However, these data also modest in size, demonstrate an accumulating radial experience in treating CTO disease with higher success rates later in the learning curve. At the current time, no randomised trials are planned or completed.

Despite the radial artery becoming a default strategy in the United Kingdom over the last decade, the current data demonstrates that in CTO-PCI, the femoral artery remains predominant. Scrutiny of the predictors of femoral access suggest that a requirement of large caliber guide catheters, dual arterial access and procedure complexity are the main drivers of this practice rather than patient defined characteristics. A particular challenge in chronic total occlusion PCI (CTO-PCI) is the frequent need for dual arterial access for contralateral visualization and wiring. Bilateral radial artery access would facilitate this technique without necessitating femoral artery puncture and although there are modest volume case series published with high success rates, this has not been a widely adopted technique.22-24 There are also case reports of novel techniques to allow contra-lateral injection with a single arterial puncture and these hold promise in minimizing future femoral arterial use.25,26 Additionally, there is often a necessity in CTO-PCI for large caliber guide catheters to allow use of bulky devices such as laser atherectomy, to facilitate CTO techniques such as trapping and snaring, and to accommodate the sheer amount of interventional kit that is often required in contemporary complex procedures.15,16 Although the physical size of the radial artery may be prohibitive for large guide catheter particularly in women, there are developments in interventional techniques and equipment that allow even 8F guides to be used radially.27-28 Therefore, although the particular challenges presented by CTO-PCI may restrict a more universal use of radial arterial access, technique and equipment development may facilitate greater use in the future.

Although acute coronary complications were similar between the femoral and radial cohorts, there was a significant increase in access site complications in the femoral cohort. This was associated with increases in transfusion, major bleeding and short-term mortality. Indeed, a further analysis of outcomes of all patients with and without femoral access site complications confirms the very significant adverse effect such an event has on outcomes. Patients experiencing an access site complication were 70 times more likely to receive a transfusion and 17 times more likely to die in the first 30 days after the procedure than patients without an access site complication. The odds ratios of these relationships were significantly greater than in other studies such as ACUITY and may be due to the baseline bleeding risk being significantly higher due to an acute presentation and the use of potent anticoagulants such as glycoprotein inhibitors.29 Additionally, the mortality expected from any elective procedure without a major complication would be predicted to be extremely low. Therefore, the impact of such an event is especially important in an elective setting and strategies to minimize access site complications (aside from radial access) including routine fluoroscopic imaging and use of vascular ultrasound may become more widely adopted.30

*Limitations*
As with any database, the robustness of the conclusions are directly related to the quality of data entered. Although there are high levels of case ascertainment and field completion within the database, the accuracy of field completion for individual centers cannot be validated. Additionally, although the BCIS dataset records 113 variables it does not record sheath size, anatomical data and in particular J-CTO score. Therefore, conclusions regarding guide catheter size and procedure complexity cannot be directly derived from the available data and can only be inferred from the devices used. Finally, as this data is registry-derived, any conclusions are potentially influenced by unmeasured confounders inherent in observational studies of this nature. For example, the higher procedural success and lower MI rates associated with radial use may be a reflection of case selection bias rather than a true reflection of radial superiority over femoral access. Additionally, the lack of a significant increase of access site complications observed with dual femoral puncture vs. single femoral puncture might be explained by confounders such as centre/referral biases.

*Conclusions*

Femoral artery access remains predominant during CTO-PCI, with case complexity and device size associated with its use. Access site complications were more frequent with femoral artery use and were strongly correlated with adverse outcomes.

**Clinical perspective**

Access site choice for PCI is a vital part of procedure planning and completion. Although many operators have switched to radial access, chronic total occlusion PCI presents several challenges to access site choice. In the current study we demonstrate that the femoral artery remains the default access site of choice even in the United Kingdom where the majority of all PCI procedures are undertaken radially. Femoral artery use was associated with more complicated CTO procedures but also associated with more access site complications. As in other studies, access site complications were closely associated with adverse outcomes.

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**Figure Legends**

Figure 1: A) Annual numbers of PCI, annual numbers of CTO-PCI, and percentage of total PCI represented by CTO-PCI in England and Wales (p<0.0001 for all annual trends); B) Annual rates of femoral puncture during CTO-PCI in England and Wales 2006-2013 (p<0.0001 for trend).

Figure 2: A) Annual rates of dual arterial access use during CTO-PCI in England and Wales 2006-2013 (p<0.0001 for trend); B) Annual rates of use of dual wrist access(p=0.0045 for trend), dual wrist and femoral access(p=0.0012 for trend), and dual femoral access (p=0.0007) during CTO-PCI in England and Wales 2006-2013.

Figure 3: A) Femoral access use by number of CTO device use (a combination of IVUS, penetration catheter, atherectomy, micro-catheter or CrossBoss use) during CTO-PCI in England and Wales 2012-2013 (p=0.001 for trend); B) Dual arterial access use by number of CTO device use during CTO-PCI (p=0.0001 for trend).

Figure 4: A) Kaplan Meier plots for 12-month mortality by femoral access site complication status in 2006-2013 procedure years (p=0.001).

**Clinical perspective**

Access site choice for PCI is a vital part of procedure planning and completion. Although many operators have switched to radial access, chronic total occlusion PCI presents several challenges to access site choice. In the current study, we demonstrate that the femoral artery remains the default access site of choice even in the United Kingdom where the majority of all PCI procedures are undertaken radially. Femoral artery use was associated with more complicated CTO procedures but also associated with more access site complications. As in other studies, access site complications were closely associated with adverse outcomes.